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Supreme Court of the United States

OCTOBER TERM, 1994

GENERAL ELECTRIC COMPANY, *et al.*,
Petitioners,

v.

PATRICIA INGRAM, *et al.*,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

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APPENDIX TO PETITION FOR A WRIT OF CERTIORARI

(PART II—OPINIONS OF DISTRICT COURT)

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APPENDIX III-A

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

George Burrell, et al. v. *Septa, et al.*	No. 86-2235
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
John Narcise, et al. v. *Septa, et al.*	No. 87-1190
Andre Williams v. *Septa, et al.*	No. 87-1258
Charles Stanbach, et al. v. *Septa, et al.*	No. 87-3227
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269

MEMORANDUM

R. F. KELLY, J. October 21, 1992

[As Amended February 1, 1993]

MOTION IN LIMINE TO EXCLUDE OPINION TESTIMONY OF JANETTE D. SHERMAN, M.D.

AND

MOTION IN LIMINE TO EXCLUDE ALL TESTIMONY CONCERNING TESTS PERFORMED AT ANTIBODY ASSAY LABORATORIES

These are two motions which are part of a series of motions *in limine* filed by Defendants Monsanto, General

Electric, Westinghouse, Septa, Budd, Amtrak and The City of Philadelphia to exclude the testimony of Plaintiffs' expert Janette D. Sherman, M.D. pursuant to Rules 702, 703 and 403 of the Federal Rules of Evidence. I have chosen to deal with these two motions in one memorandum because the expert testimony produced by Defendants dealt with both motions and these motions involved matters that are closely related.

Plaintiffs proposed to offer as evidence the opinions of Dr. Sherman that:

1. Thirteen Plaintiffs were exposed to PCBs and contaminates of dielectric fluid;

2. As a result, each has suffered adverse health effects;

3. Each of these Plaintiffs is at an increased risk of developing cancer, as well as other illnesses; and

4. The Plaintiffs require regular medical monitoring.

In their motion, Defendants contend that Dr. Sherman's proposed testimony should be excluded because:

1. Her professional training and experience did not qualify her to render such opinion under Rule 702 of the Federal Rules of Evidence ("Rule 702");

2. Dr. Sherman failed to base her opinions upon a reliable scientific technique and for that reason they are inadmissible under Fed. R. Evid. 702;

3. Dr. Sherman failed to base her opinions on data upon which experts in the relevant fields reasonably rely upon and for that reason are inadmissible under Rule 703 of the Federal Rules of Evidence ("Rule 703"); and

4. Dr. Sherman's opinions are more likely to confuse or mislead the jury than to contribute evidence of probative value and should therefore be excluded under Rule 403 of the Federal Rules of Evidence ("Rule 403").

Attached as exhibits to this motion were the affidavits of Jordan N. Fink, M.D., Betty Lowell Cottle, M.D., F.A.C.A., Michael R. Weitekamp, M.D., F.A.C.P., Charles T. Lee, Jr., M.D., F.A.C.P., Paul M. Roediger, M.D., F.A.C.P., Elliott Vesell, M.D., Sc.D., Ronald J. Harbeck, Ph.D., James J. Leyden, M.D., S. Michael Phillips, M.D., Marie A. Savard, M.D. and Robert Wilson Morgan, M.D., S.M. Hyg.

Hearings were held on this and the other motions filed by the parties on July 28, 29, 30, 31 and August 3, 1992. On August 7, 1992, all parties were given the opportunity to argue the motions *in limine* and the motion for summary judgment pending before the Court. From those hearings, this Court makes the following:

FINDINGS OF FACT

1. Dr. Sherman has a bachelor's degree in both biology and chemistry and received her medical degree from Wayne State University in 1964. Sherman T. 92-93. She completed a one-year rotating internship at Wayne State Hospitals. Sherman T. 96.

2. Dr. Sherman does not diagnose, treat or care for individuals on an ongoing medical basis, and has not done so for the past sixteen years. Sherman T. 132; Sherman Dep. 53.[1] Although Dr. Sherman stated in her courtroom testimony that she maintained an office in Detroit until 1988 and that she still sees patients on a regular basis, I find that those are individuals that she is seeing in the context of litigation. Sherman T. 132. In 1976, she began to devote substantially all her time to litigation consulting work. Sherman T. 132-33.

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[1] Sherman Dep. refers to the deposition testimony of Janette Sherman, M.D. taken on May 19, May 20, June 5 and June 19, 1992.

3. Since 1976, Dr. Sherman ceased doing general internal medicine and has done mostly consulting in the field of internal medicine and toxicology. Since 1976, substantially all of the income that she generated from her professional activities has come from work in cases that were involved in litigation. Sherman Dep. 48-49; Sherman T. 133. She has been involved in over 8,000 cases since 1976, and has given over 800 depositions, nearly all of them in worker's compensation cases. Sherman T. 134; Sherman Dep. 70-71. In all but two of those cases her testimony has been for plaintiffs. Sherman T. 139-40. Dr. Sherman could not remember a single instance in which she examined an individual supposedly exposed to PCBs, where she concluded that PCBs had *not* caused adverse health effects. Sherman T. 140-41.

4. Dr. Sherman does not currently have admitting privileges at any hospital in the country and has not had admitting privileges since 1976. Sherman T. 135; Sherman Dep. 52-54. Dr. Sherman is licensed to practice medicine in Virginia, California, Hawaii and Michigan.

5. Although Dr. Sherman lists two "offices', one in Hawaii and one in Virginia, these "offices" are post office boxes; Dr. Sherman has residences in both of these locales, and has chosen to designate part of her residence as an office. Sherman Dep. 50-51. She has no office at which she can examine patients, "I use colleague's office in various places wherever it is needed."

Sherman T. 94.

6. Dr. Sherman offers herself as an expert in internal medicine and toxicology. Sherman Dep. 44. Dr. Sherman admits that she is not an expert in immunology. Sherman Dep. 229-30; oncology, Sherman Dep. 361; neurology, Sherman Dep. 592; psychiatry, Sherman Dep. 593; dermatology, Sherman Dep. 690; epidemiology, Sherman Dep. 711-12; and "exposure assessment", Sherman Dep. 174-75.

7. Dr. Sherman is not board-certified in any medical discipline, including the two in which she claims to be an expert. Sherman T. 137-39. She testified that she was board-certified in general medicine as a result of passing the National Board of Medical Examiners' test in 1975. Sherman T. 138; Sherman Dep. 56. However, this test is merely a qualifying examination for licensure as a medical doctor, and is normally taken by seniors in medical school. This is not a certification of any kind. Fink T. 21; Morgan T. 106.

8. Dr. Sherman testified that she is "Board-eligible" in internal medicine. However, she has never taken that board examination, and has no intention of doing so. Sherman T. 136; Sherman Dep. 55.

9. Dr. Sherman testified that she became an expert in toxicology in "the 80s" through experience, reading, writing, teaching, evaluating patients [and] course work. Sherman Dep. 413. Dr. Sherman took no toxicology courses in medical school and her training does not indicate that she is an expert in that discipline. Roediger T. 108. She is not board-certified in toxicology. Sherman T. 137.

10. Defendants at the motion *in limine* hearing called Dr. Jordan Norman Fink, M.D. Dr. Fink graduated from the University of Wisconsin with a B.S. degree in 1956 and M.D. degree in 1959. He completed a one-year rotating internship at Mt. Sinai Hospital in Milwaukee and a three-year residency in internal medicine at Marquette University in Milwaukee. He is currently a Professor of Medicine and Chief of the Allergy Immunology Division at the Medical College of Wisconsin. For the past twenty-five years, he has been involved in research dealing with immune responses of the lung, unusual lung diseases and experimental models of those lung diseases. Over the years, he has produced approximately 237 publications in peer review journals and scientific journals. He is licensed to practice medicine in Wisconsin, California and Ari-

zona. He is currently on the committee at the Medical College of Wisconsin that oversees clinical practice. He is board-certified in internal medicine, allergy and immunology. He currently teaches immunology at the Medical College of Wisconsin. His medical practice currently involves seeing approximately 16 new patients a week and about 100 return visits per week of other patients. Fink T. 13-16.

11. Dr. Fink testified that Dr. Sherman is unqualified to offer expert testimony in the fields of internal medicine or immunology. Fink T. 19-20, 28. In support of that opinion, he testified that she did not adhere to the principles of internal medicine in reaching her conclusions, and that her deposition testimony displayed fundamental deficits in her knowledge of internal medicine. Fink T. 20. Dr. Fink recounted numerous errors on basic medical terminology and principles made by Dr. Sherman, and concluded that these fundamental errors indicate Dr. Sherman's lack of qualifications. Fink T. 22-27. He testified that Dr. Sherman exhibited "major deficits" in medical knowledge and that "these items should be in the forefront of knowledge of any internist, any resident, and any medical student." Fink T. 27. He also testified that Dr. Sherman's own testimony shows that she does not understand the functioning of the immune system; does not understand the immune tests that she ordered and purported to rely upon; and that she is not qualified to interpret those tests. Fink T. 28, 33, 36, 38. In addition, Dr. Fink testified that Dr. Sherman did not appear to follow any methodology other than to blame all Plaintiffs' illnesses on PCBs. Fink T. 40, 42-43. She failed to consider alternative causes for the Plaintiffs' various illnesses, and that failure renders unreliable her opinion that these illnesses were caused by PCB exposure. Fink T. 41-42. According to Dr. Fink, the consideration of alternative causes in evaluating a disease or condition is "the basic practice of internal medicine." Fink T. 43. Dr. Fink also testified that Dr. Sherman's use of and reliance on certain

immunological data obtained from Antibody Assay Laboratories ("AAL") for ten of the Plaintiffs in this case was unacceptable medical practice. He testified that the AAL data, which form a substantial basis for Dr. Sherman's opinion, are not reliable, and not of the type reasonably relied upon by experts for the purposes Dr. Sherman attempts to use them. Fink T. 36, 44. Indeed, Dr. Fink testified that "no physician would order these tests in the absence of any clinical evidence of an immunological abnormality." Fink T. 45-46.

12. Defendants also called Dr. Paul Roediger as an expert witness at the *in limine* hearing. Dr. Roediger graduated from Princeton University in 1954 with a B.A. degree and from Jefferson Medical College in 1958 with a M.D. degree. He completed a one-year rotating internship at Abington Memorial Hospital and a three-year additional residency in internal medicine. After that he entered into medical practice at Abington Memorial Hospital and in 1963 was appointed Director of Medical Education and remains in that position at the present time. He spends about 20 hours a week controlling the administrative aspects of the 80 residents in training at Abington Memorial Hospital. He was appointed Physician and Chief of General Internal Medicine in 1972 and holds that position at the present time. He is board-certified in internal medicine. Roediger T. 94-97.

13. Dr. Roediger testified that Dr. Sherman was not qualified as an expert in internal medicine, toxicology, or immunology. Roediger T. 98-99, 108, 114. He testified that Dr. Sherman could not receive admitting privileges at Abington Memorial Hospital, Roediger T. 103, and that Abington standards for granting privileges were similar to those employed in most hospitals across the country. Roediger T. 99-101. Further, he agreed with Dr. Fink's testimony regarding Dr. Sherman's ignorance of the basic principles of internal medicine, and cited an additional example that Dr. Sherman did not know the difference

between plasma and serum. Roediger T. 108-09. Dr. Roediger also testified that Dr. Sherman did not follow reliable methodology in formulating her opinion in this case since she did not order standard laboratory tests for any of the Plaintiffs, examined only three of the thirteen Plaintiffs on whom she opines, and failed to consider alternative causes. Roediger T. 119-22.

14. Dr. James Leyden was also called by Defendants as an expert in the field of dermatology. He graduated from the University of Pennsylvania Medical School in 1966 and completed a residency in dermatology at Penn where he later joined the faculty and for fifteen years he has had the additional responsibility of being the Chief of the Dermatology Clinic. He currently sees patients, teachers and does research. He sees on the average approximately 120 patients a week. Dr. Leyden has been a full professor at Penn Medical School since approximately 1983 and is board-certified in dermatology. In the field of research, on two occasions, he has won the gold medal from the American Academy of Dermatology. Leyden T. 143-47.

15. Dr. Leyden testified that Dr. Sherman was not an expert in dermatology, and was not qualified to diagnose chloracne or any dermatologic condition. Leyden T. 152. He described the marked difference between chloracne, a condition associated with exposure to halogenated hydro carbons, and acne vulgaris, which is common acne. Leyden T. 153-54, 156-57. He testified that any physician qualified to diagnose dermatologic conditions would easily be able to distinguish between the appearance of those two conditions. Leyden T. 154. As a matter of fact, Dr. Leyden testified that he could tell the difference between the two conditions at fifty paces. Leyden T. 160. Since Dr. Sherman testified that the two conditions are identical in appearance, Dr. Leyden found that she plainly was not qualified to diagnose chloracne in any of the Plaintiffs in this case. Leyden T. 154-55. Dr. Leyden

pointed out that Dr. Sherman's methodology in making such diagnoses was nonexistent. Leyden T. 157.

16. Defendants called an expert witness, Dr. Ronald Harbeck, who is the Director of the Clinical Laboratories, the Director of the Diagnostic Immunology Laboratory and a member of the Department of Medicine at Ashland Jewish Center for Immunology and Respiratory Medicine in Denver, Colorado. He holds appointments to three departments at the University of Colorado School of Medicine, those being the Department of Pathology, Microbiology and Department of Medicine. The National Jewish Center for Immunology and Respiratory Medicine is an institution which conducts research in respiratory diseases and immunology. Its research programs are recognized world-wide and has recently been mentioned as one of the top ten independent research institutions in the United States. Dr. Harbeck performs immunology testing on a daily basis. He has over 65 publications in peer review journals and has written a textbook in diagnostic immunology which was published in 1991. He is board-certified by the American Academy of Microbiology and has a Ph.D. in microbiology. Harbeck T. 73-75.

17. Dr. Harbeck's testimony was directed toward the immunologic data that Dr. Sherman ordered from AAL. He testified that the AAL results were totally unreliable, and would not be relied upon by experts for any conclusion. Harbeck T. 76. He explained that AAL has not received accreditation from the College of American Pathologists ("CAP"), and that the quality control procedures it used were totally inadequate. Harbeck T. 84.[2] He explained the reasons for the CAP accreditation program and that the test results of a lab which fails to obtain this accreditation are unreliable. Harbeck T. 85-86. He also noted that AAL did not follow accepted

[2] Dr. Harbeck has inspected labs on behalf of CAP. Harbeck T. 84.

laboratory methodology in performing several standard analytic procedures. Harbeck T. 81-82. Dr. Harbeck concluded that any results obtained by AAL were completely untrustworthy. Harbeck T. 86.

18. Robert W. Morgan, M.D., S.M. Hyg., is a graduate of Harvard University School of Public Health and the University of British Columbia School of Medicine. He is certified in occupational medicine by the American Board of Preventive Medicine and he is a Fellow of The American College of Epidemiology. He has taught both preventive medicine and epidemiology at the University of Toronto, and he has served as Director of the Stanford Research Internal Center for Community Health Studies. He has published in the fields of occupational health, preventive medicine and epidemiology. Dr. Morgan testified that Dr. Sherman "doesn't have the qualifications that one would normally expect of an internist," and that she also was not qualified in the field of occupational medicine. Morgan T. 107-13. He noted that Dr. Sherman had not practiced clinical medicine for 16 years, and cited several errors in basic anatomy and immunology that Dr. Sherman made at her deposition. Morgan T. 111-13. Dr. Morgan also testified that Dr. Sherman did not employ any reliable methodology in concluding that PCB exposure was the cause of the various illnesses of which the Plaintiffs complained. Morgan T. 108.

19. Michael R. Weitekamp, M.D., F.A.C.P., is Chief of the division of General Internal Medicine at Hershey Medical Center and is an associate professor of medicine at the Pennsylvania State University Medical School. From 1985 to 1990, he was Chairman of the Department of Medicine at the Polyclinic Medical in Harrisburg, Pennsylvania. He graduated from Georgetown University Medical School and was trained in internal medicine and infectious diseases at Hershey Medical Center. Dr. Weitekamp is certified by the American Board of Internal Medicine in both internal medicine and infectious dis-

eases, and actively engaged in the practice and teaching of both of these disciplines. Dr. Weitekamp is a member of the Penn State Department of Medicines Resident Clinical Competency Committee, and he serves on the Medical Education and Quality Assurance Committees of the Polyclinic Medical Center. Dr. Weitekamp testified that Dr. Sherman was unqualified in the fields of internal medicine and immunology. Weitekamp T. 32, 51. He noted many errors regarding basic principals of internal medicine and immunology that Dr. Sherman made in her deposition. Weitekamp T. 36-37, 39, 51. He stated that most of the medical students and residents under his supervision would not make such errors. Weitekamp T. 38-39. Dr. Weitekamp also testified that Dr. Sherman's failure to perform differential diagnoses for the Plaintiffs' illnesses constitutes a violation of "the whole process that is really the hallmark of the internist," and thus her methodology is totally unreliable. Weitekamp T. 62.

20. Dr. Stanley M. Phillips was called on behalf of Defendants as an expert in internal medicine, immunology and allergy. Dr. Phillips is currently employed at the University of Pennsylvania Medical School as a full time professor of medicine with a subpecialty of allegery and immunology at the University of Pennsylvania. Phillips T. 3. He is a senior scholar in clinical epidemiology at University of Pennsylvania and a senior consultant in medicine and allergy in immunology at the Philadelphia Veterans Administration Hospital and a consultant to the Smith-Kline Beckman Corporation in the field of immunology. He has served on the faculties of Harvard University and George Washington University. He has edited two books and over a hundred publications in peer review journals, and has served on the editorial board of review of the American College of Physicians. He has served on the editorial board of the Journal of Immunology, the Journal of Allergy and Clinical Immunology, and the journal of clinical investigation in the New England Journal of Medicine. In addition to his responsibili-

ties at the University of Pennsylvania Medical School, he spends a third of his time in clinical practice taking care of patients in private practice where he sees patients with internal medicine problems as well as allergy immunology problems. Phillips T. 3-8. Dr. Phillips testified that the immunology test ordered by Dr. Sherman and performed by AAL are of no clinical significance, and are neither important nor meaningful in the clinical evaluation of a patient. Phillips T. 10. In fact Dr. Phillips testified that the tests "probably would be more misleading and dangerous than helpful." Phillips T. 10. According to Dr. Phillips, many of the tests performed by AAL have no clinical significance, are useless for any clinical purposes, and would not be performed by any reputable laboratory. Phillips T. 17-20. Dr. Phillips further testified that AAL test results are not scientifically valid, that such tests are not reasonably relied upon by the medical or scientific community, and that the methodology utilized by AAL in performing the tests were completely unreliable. Phillips T. 17-21, 27, 35, 41.

21. In her deposition testimony, Dr. Sherman states that John Ingram, Jr.'s myelin auto-antibodies reflect "damage to his myelin cells, which are on the central nervous system." Sherman Dep. 259. Dr. Fink testified that "myelin is a lipid coating of the nerve fibers. There is no such animal as a myelin cell. Myelin is made by a cell called Schwann's cell." Fink T. 24-25; *see also* Morgan T. 111-12; Weitekamp T. 37-38.

22. Dr. Sherman states that the difference between plasma and serum is that "[p]lasma has the proteins removed." Sherman Dep. 143. Serum, not plasma, has the proteins or clotting factors removed. As Dr. Roediger testified, any medical student or resident would know the difference between the two. Roediger T. 109; *see also* Weitekamp T. 38.

23. According to Dr. Sherman, deoxyribonucleic acid ("DNA") consists of four base pairs—"adonine, guani-

dine, thymidine and uridine." Sherman Dep. 359. This is wrong—Dr. Sherman omitted cytosine, and inserted uridine, which is not found in DNA. Weitekamp T. 38-39. This mistake is particularly noteworthy because Dr. Sherman has testified that PCBs interact with DNA to produce mutations which ultimately cause cancer in humans. Sherman Dep. 351-58.

24. Dr. Sherman testified that candida infections are not common in young children. Sherman Dep. 856. In fact, candida, one of the causes of diaper rash, is very common in young children. Weitekamp T. 58-59.

25. A large part of Dr. Sherman's medical opinions in this case were based on the results of immunological tests by AAL which she ordered for ten Plaintiffs. She testified that she found "an overall pattern throughout these ten people of serious derangement of immunological function. And more than likely, I believe you will see an increased rate of malignancy among these people, which is, I believe, reflected early by the abnormal findings." Sherman Dep. 648. However, when asked about those tests at Sherman Dep. 298,

> Q. What are the different things that they measure?
>
> A. That you'll have to ask Dr. Broughton.

Again at Sherman Dep. 300,

> Q. What is the predicted significance of an elevated lymphocyte test stimulated by PHA?
>
> A. You'll have to ask Doctor Broughton for that —what those sophisticated tests mean.

Again at Sherman 300,

> Q. OK, now does the measure of the T cells reflected in the PHA stimulation have for you any significance in predicting future health defects of an individual?
>
> A. I don't know.

See also Sherman Dep. 305-07, 473, 646-48, 944.

Dr. Sherman is not board-certified in immunology, and she admits that she is not an expert in that field. Sherman T. 137; Sherman Dep. 229-30.

26. As to the significance of the TA1 positive cells [CD 35], she noted that it is "one of the subsets of the T helper cells," but beyond that, Dr. Sherman did not have any other information. Sherman Dep. 470-72. As to [why] one would order such a test she replied, "[Y]ou'll have to ask Dr. [Broughton]." Sherman Dep. 473.[3]

27. Dr. Sherman was not qualified to interpret the results of those tests. Fink T. 28. [Dr. Sherman "admits that she is not [an expert in immunology] and I believe from her testimony that she absolutely is not competent to analyze immune tests . . . ."]; Roediger T. 116-17; Weitekamp T. 60. This point is conceded by Dr. Sherman in her deposition. Sherman Dep. 646-48, 944.

28. At times, Dr. Sherman assigns incorrect meanings to certain of the immune tests. She states, for example, that the anti-nuclear antibody tests tell one "that there has been antigenic damage to the nuclear portion of the cell," Sherman T. 211; that the anti-smooth muscle antibody tests "determine[s] if there has been any antigenic damage to the smooth muscle cells," Sherman T. 212 and that the anti-mitochondrial antibody determines "[w]hether there has been damage to the mitochondrial of the cells," Sherman T. 213.

Drs. Fink, Phillips, and Weitekamp testified that all this is incorrect. Fink T. 33 [Dr. Sherman's diagnosis of "antigenic damage" to the smooth muscle cells is "a false concept that she has. There is no antigenic damage. The antigens don't damage."]; Phillips T. 15-17; Weitekamp T. 52-53.

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[3] Dr. Broughton is the director of Antibody Assay Laboratories. The Plaintiffs have not designated him as an expert and he did not testify at the *in limine* hearing.

29. Dr. Sherman states that T suppressor cells can cause B-cells to produce antibodies. Sherman Dep. 218. Dr. Fink, in his testimony, stated that that is absolutely incorrect. "Suppressor cells suppress. That is why they are called suppressor cells. They suppress antibody formations." Fink T. 34-35.

30. When asked how many classes of antibodies there are, Dr. Sherman replied, "I don't think I've counted. I don't really. I don't really know." Sherman Dep. 264. Dr. Fink testified that "There [are] five classes. Everybody knows that." Fink T. 28-29. He went on to state that that is something that a medical student would know, that it is taught in all medical schools and taught in continuing medical education courses. Dr. Sherman stated also that she could not remember the difference between IgG and IgM, or the significance of IgE. Sherman Dep. 330, 470. As Dr. Fink testified, this is "an insult" because it is "absolutely basic immunology." Fink T. 29-30.

31. The proper methodology in determining the cause of a particular individual's illness is to examine first for the most common causes of that condition. Only after eliminating those causes can one move to the more remote causes. Roediger T. 119-121. According to Dr. Roediger, the answers that Dr. Sherman gave in her testimony do not reflect an understanding of the common identifiable causes for diseases of hypertension, diabetes and asthma. Roediger T. 121.

32. According to Dr. Sherman, there are two types of asthma: "fatal and non-fatal." Sherman Dep. 438 ("that's all I can think of"). She also states that the known causes of asthma include "profound respiratory infection," "exposure to some of the organo phosphate pesticides" and "damage to the lung for whatever reason." Sherman Dep. 437. As Dr. Fink states, there are two types of asthma, extrinsic and intrinsic, not "fatal" and not "non-fatal." Fink T. 26-27. Dr. Weitekamp explained that it is erroneous and meaningless to classify asthma or any

other disease process as "fatal" or "non-fatal." Weitekamp T. 42-43. Dr. Fink termed that distinction "silly." Fink T. 26.

33. According to Dr. Sherman, the only causes of hypertension are "endocrine, anatomical abnormalities of the kidney, chronic kidney infection and xenobiotic damage to the kidneys." Sherman Dep. 206-07. Almost all of the hypertension seen in our society is called "essential hypertension," the cause of which is unknown. Weitekamp T. 46; Fink T. 22-23; Morgan T. 108. Furthermore, as to the known causes of hypertension, Dr. Sherman omitted family history and lifestyle, two of the most prevalent known causes. Fink T. 22-23.

34. According to Dr. Sherman, the only causes of diabetes are "chemicals and radiation." Sherman Dep. 443 ("I can't think of anything else"). As to this, Dr. Fink states, "it's common in internal medicine to know that diabetes is an idiopathic disease and we don't know the cause. Except in the juveniles, where diabetes may be an immune disorder in which antibodies are formed against the cells which manufacture the insulin." Fink T. 26; *see also* Weitekamp T. 43.

35. According to Dr. Sherman, hyperpigmentation is due to "T cells which start in the thymus" carrying cells to the skin, and those T cells cause the pigmentation. Sherman Dep. 245-46. Dr. Fink states, "this doesn't make sense. That's wrong." Fink T. 24; *see also* Morgan T. 111 ("I have never heard any theory even remotely resembling that."); Weitekamp T. 44.

36. Drs. Weitekamp and Roediger explained that in ordering and interpreting medical tests, one must understand the concepts of "sensitivity" and "specificity." As Dr. Roediger states, if a physician does not understand these concepts, she cannot order or interpret any type of medical tests. Roediger T. 113-114; *see also* Weitekamp T. 57 ("I don't think you can apply a test to clinical

practice, unless you have an understanding of sensitivity and specificity."). Dr. Sherman admits that she does not know the difference between these two terms. Sherman Dep. 566. (Q. Doctor, do you know what is referred to as the sensitivity of a test? A. No. Q. What about the specificity of a test? Do you know what that refers to? A. No.) Dr. Sherman also did not know what a positive or negative predictive value means. Sherman Dep. 567. She does not know the distinction between "incidence" and "prevalence". Sherman Dep. 715-16. All of these are distinctions commonly made by and well known to physicians. Roediger T. 111-12; Weitekamp T. 57. Dr. Weitekamp explained that without this basic knowledge, Dr. Sherman is not only unqualified to order and interpret specific diagnostic tests but she also is incompetent to design a medical monitoring plan. "I would have to say that somebody who doesn't seem to have a firm foundation in clinical epidemiology, which includes an understanding of sensitivity, specificity and predictive value of testing, that individual should not be making recommendations for screening tests." Weitekamp T. 70. Those made by Dr. Sherman are "certainly not" based upon recognized scientific technique or data internists reasonably rely upon. Weitekamp T. 71.

37. Dr. Sherman testified that she can distinguish between chloracne, a skin condition associated with heavy exposure to halogenated hydrocarbons, and common acne (acne vulgaris). She opined that two Plaintiffs may have suffered from chloracne. Yet, she cannot describe the difference in appearance between chloracne and common acne. Sherman Dep. 686-87. As explained by Dr. James J. Leyden, Professor of Dermatology at the University of Pennsylvania School of Medicine and one of the four or five nationally recognized experts on acne, the characteristics and distribution of the lesions of these two forms of acne are totally different, and their appearance on biopsy is distinct. Leyden T. 147-49, 153.

38. Dr. Sherman testified that she has seen chloracne and "[i]t looks like your standard so-called teenage acne." Sherman Dep. 686. But Dr. Leyden testified, "that's not correct at all . . . chloracne is very distinctive." Leyden T. 153. Dr. Leyden also testified that Dr. Sherman was plainly wrong in stating that "we don't know whether ordinary teenage acne isn't really chloracne, you see, without a history you don't know." Sherman Dep. 687. As Dr. Leyden stated, "she may not know, but those of us who work in this field sure do know the difference and we know how to tell the difference by looking, and we've known how to do that for a long time." Leyden T. 154. Asked whether his residents could distinguish acne from chloracne, Dr. Leyden responded, "Yes, absolutely. In fact, if they didn't . . . I'd feel compelled to resign." Leyden T. 154.

39. At the hearing, Dr. Leyden displayed two color photographs—one of a man with chloracne, and one of a man with common acne. *See* Defendants' *In Limine* Exhibit 6. The difference between the two conditions is striking. Dr. Leyden testified that any physician who purports to be able to diagnose chloracne can easily distinguish between that condition and acne vulgaris. Leyden T. 154. He concluded that since Dr. Sherman cannot make that distinction, she is clearly unqualified to diagnose any of the Plaintiffs with chloracne. Leyden T. 155.

40. Drs. Fink, Weitekamp, Roediger, Leyden, and Morgan uniformly concluded that Dr. Sherman is not qualified to offer an expert opinion in internal medicine, toxicology, immunology, or any other field of medicine. Fink T. 19-20, 28, 36, 38; Weitekamp T. 32, 60; Roediger T. 98-99, 108, 114; Leyden T. 152; Morgan T. 107, 111, 113. By virtue of their own experience and training, their responsibility for teaching medical students and residents, and the roles they play in evaluating both students and other physicians, these physicians are emi-

nently qualified to determine what qualifications are necessary before one can be considered an expert in their respective fields of medicine.

41. In support of their conclusion, these doctors all pointed to Dr. Sherman's lack of formal qualifications, her sixteen-year absence from the clinical practice of medicine, and the impact that has on her current knowledge of medicine. Roediger T. 98-104; Weitekamp T. 60. They find that this lack of training and experience manifests itself in Dr. Sherman's failure to understand basic concepts of internal medicine, failure to understand the immune system tests she ordered from AAL, and misinterpretation of the significance of the immune test results. In particular, Dr. Fink described her theory that the immune system is not activated unless there is "damage to the cells" as totally false—according to Dr. Fink, this reflects a fundamental misunderstanding of the human immune system. Fink T. 33, 38. The experts found her unqualified to be on their respective hospital or lab staffs, unqualified to diagnose medical conditions, and unqualified to treat patients. This evidence is persuasive. The Court finds that Dr. Sherman is not qualified as an expert in any field of science or medicine, and her testimony would be of no assistance to the trier of fact.

42. For ten Plaintiffs, Dr. Sherman bases her opinions solely on her review of medical records and of questionnaires completed by the Plaintiffs and their attorneys. Sherman T. 144. Dr. Sherman examined only three of the thirteen Plaintiffs as to whom she offers opinions.[4] Sherman T. 143.

43. Dr. Sherman did not order any of the standard medical or laboratory testing that would typically accompany an ordinary physical examination, such as standard blood chemistry, urinalysis, liver function, kidney function, or pulmonary function tests. Sherman T. 150-51, 153-54.

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[4] Amber Burell, Andre Williams and Bessie Cunningham.

She did not ask that any Plaintiff be tested for PCBs or any of the "contaminants" of dielectric fluids that she contends caused them to suffer alleged adverse health effects. Sherman Dep. 34.

44. The only tests Dr. Sherman requested were immunology "tests" offered as part of a "Chemical Injury Kit" by AAL which is located in Santa Ana, California. Sherman T. 150, 154.[5] She selected AAL because of the favorable experiences she had with that lab and its director in the past. Sherman T. 151. Yet, there are several reliable labs in the Philadelphia area which could have performed the immune tests Dr. Sherman requested. Phillips T. 36. The AAL "Kit" was shipped to Plaintiff's counsel. Dr. Sherman does not know whether the "Kit's" instructions were followed, when or how the Plaintiffs' blood was drawn, or when the blood was shipped to California. Sherman T. 156; Sherman Dep. 287 ("I was not there.")

45. With the exception of the three Plaintiffs who she examined, the only information Dr. Sherman had about these Plaintiffs were certain medical records provided by Plaintiffs' attorneys and the AAL results. With the exception of two of the thirteen Plaintiffs, none of the treating physicians even mentioned PCBs in the Plaintiffs' medical records (Sherman T. 147), much less concluded that PCBs caused any illness. Dr. Sherman admits that in reviewing medical records she did not make her own differential diagnoses apart from those made by the treating physicians. Sherman T. 161.

46. Nonetheless, Dr. Sherman cites exposure to PCBs as a "significant contributing cause" of virtually every

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[5] Dr. Sherman said she believes all of the Plaintiffs should have a complete history and physical, complete blood count and differential, an "SMA-12," and "lipids," before trial—but she has not yet requseted that these tests be run. Sherman Dep. 31-32. She acknowledges that she "could have" asked for these tests at the time she requested the immunology tests but did not do so. Sherman Dep. 144. She did not recommend PCB fat tests, but states they "would be a very good idea." Sherman Dep. 34, 68.

condition or illness described in the medical records she reviewed. Fink T. 40; Roediger T. 135-36. These include such common diseases as asthma, diabetes, elevated lipids, hypertension, lung disease, heart disease, cancer, respiratory infections, interference with the immune system, heart attacks, elevated liver function tests, arthritis, pain in the joints, headaches, sinusitis, skin rashes, and various other illnesses. *See* Sherman Report dated April 6, 1992.

47. In this case, Dr. Sherman has failed to utilize any reliable process to form opinions as to the relationship between any alleged exposure to PCBs and any of Plaintiffs' alleged health effects. As Dr. Fink testified, she simply blamed everything—even the most common illnesses—on PCBs. Fink T. 40-42.

48. Asked to describe Dr. Sherman's methodology, Dr. Fink testified, "I couldn't find any." Fink T. 43. Dr. Fink pointed out that it is standard medical practice to first perform a physical, obtain the necessary test results, and make a differential diagnosis, but Dr. Sherman did not follow these procedures. Fink T. 17-19. "She went from patient complaint to PCBs. Made no difference what the patient said, it was PCBs. That's not accepted medical practice." Fink T. 40. "[W]hen she was asked about alternative causes, she said there were none, it was all PCBs." Fink T. 42.

49. Dr. Roediger explained that Dr. Sherman only examined three patients; she did not examine any of the other individuals involved in the litigation. Roediger T. 118-21. He testified that it is "standard medical practice" to do a physical examination before forming a medical judgment, and that a physician cannot base a differential diagnosis solely on a review of pre-existing medical records. Roediger T. 122-24.

50. Dr. Leyden testified that he was unable to discern that Dr. Sherman followed any methodology in reaching

the conclusion that two Plaintiffs suffered from chloracne. She just "seemed to declare it as an example of chloracne." Leyden T. 157.

51. Dr. Weitekamp testified that "[i]t certainly was not apparent from her testimony" that Dr. Sherman actually performed a differential diagnosis on the Plaintiffs. Weitekamp T. 65. "[H]aving read the testimony and having seen how she tried to link each of those various complaints to PCB exposure, without really entertaining other possible causes, I would say that that's inappropriate." Weitekamp T. 66. "It's shooting from the hip, very opinionated. I don't know any other way to describe it." Weitekamp T. 66. "I do not feel that she used reliable scientific technique in formulating her opinions." Weitekamp T. 67.

52. Dr. Weitekamp testified that Dr. Sherman's methodology is equally flawed with respect to her medical monitoring opinions. Those opinions are "certainly not" based upon reliable scientific technique. Weitekamp T. 70-71.

53. Dr. Morgan testified that he was not aware that Dr. Sherman based any of her opinions on "any methodology." Morgan T. 103. "I couldn't detect any methodology." Morgan T. 108.

54. As Drs. Fink, Roediger, Weitekamp, and Morgan testified, a differential diagnosis—where the physician either rules in or rules out alternative causes for diseases—is the hallmark of internal medicine. According to Dr. Fink, considering alternative causes is "the basic practice of internal medicine. That's what the internist does, makes a diagnosis by taking the entire picture, outlining what the possibilities [are] and then honing down based on his knowledge and experience and literature that he has read, et cetera, in making a diagnosis." Fink T. 43; *see also* Roediger T. 118; Weitekamp T. 60-62; Morgan T. 109. These doctors explain that in making a determination as to the cause of a disease, an internist must start with the

most common causes of the condition. Only after eliminating those causes can more esoteric causes he considered. Roediger T. 117-19.

55. Dr. Sherman does not follow this procedure. She assigns PCBs as the cause of a disease and does not consider, and rule out, *any* alternative causes. For instance, although she testified that PCBs caused the following illnesses, she conceded that she did not consider and rule out any alternative causes for these illnesses:

John Ingram, Sr.'s hypertension, Sherman T. 149-50;

John Ingram, Sr.'s elevated T. suppressor and T helper cells, Sherman T. 152-53;

Charles Stanbach's stomach cancer, Sherman Dep. 388;

Patricia Ingram's asthma, Sherman T. 157-58;

Patricia Ingram's diabetes, Sherman Dep. 444-45;

Ten Plaintiffs' "overactive immune systems," Sherman Dep. 640-41;

Andre Williams' episcleritis, Sherman T. 165;

Patricia Burrell's dizziness, Sherman Dep. 698;

Matthew Cunningham's anemia, Sherman T. 165-66.

In fact, as Dr. Fink correctly noted, Dr. Sherman did not conduct any meaningful evaluations of possible diseases and attempt to consider or rule out those causes. Fink T. 42-43.

56. Dr. Sherman examined only three of the thirteen Plaintiffs on whom she offers an opinion in this case. As to the ten she did not examine, Dr. Sherman conceded that she did not perform differential diagnoses for *any* of the illnesses documented in their medical records. Sherman T. 160-62. She purports to rely on these medical records as the sole basis for her opinion that PCBs caused these Plaintiffs' past and present conditions, claiming that

the treating physicians performed the required differential diagnosis. Sherman T. 159-62. Yet, with two possible exceptions, *none* of the treating physicians found that PCBs were associated in any way with their patients' illnesses. Sherman T. 147. Dr. Sherman's explanation for this—that the treating physicians did not know about the Plaintiffs' PCB exposure—is not credible, since she admitted that she has never spoken to any treating physician. Sherman T. 147-48.

57. In this case, where she did not examine ten out of thirteen Plaintiffs about whom she testified, Dr. Sherman purported to rely on the Plaintiffs' medical records in making her judgment (even though those records did not include any finding that PCBs caused any of these problems). Dr. Sherman testified before this Court that "of course" it was "generally accepted" to rely on such medical records. Sherman T. 120. Yet earlier this year, in a case in Florida where Dr. Sherman had not reviewed the medical records of certain plaintiffs before rendering her opinion, she testified that such records are unreliable for this purpose. In *Woodman v. United States*, on direct examination by plaintiffs' attorney, Dr. Sherman gave the following sworn testimony:

> Medical records, oh, my, they are very difficult to use because frequently the patient goes in with roaring diarrhea and they have also got a headache, the doctor is making all of his attention, or her attention on the diarrhea, don't ask about the headache, many times, at least a lot of the records I read are almost illegible. Many physicians don't do a review of systems, they only attend to the immediate problem that the person is in there for. Many times patients, if they have been in six times to complain of the same thing don't say anything anymore, they get discouraged and just figure, well, there is no point.

Woodman testimony, February 18, 1992, p. 55. Then she gave the following point-blank answers to questions from the trial judge:

The Court: I'm really—I'm perplexed, Dr. Sherman, with respect to Steven, and I think it's Candra who had an examination. I have understood that you take the position that, in your professional judgment, the most reliable source for your diagnosis is your personal interview with the physical examination of a patient.

The Witness: Yes.

The Court: That you do not rely upon preexisting medical records because of the propensity toward inaccuracy.

The Witness: That's correct.

The Court: Bias and so forth.

The Witness: Mostly omissions.

The Court: I believe that you said that surgery and pathology reports are generally—you had found them accurate.

The Witness: And hospitalization reports.

The Court: But day-by-day medical records kept by your colleagues in the profession are not reliable for the purposes that you're here to testify.

The Witness: In general, that is correct.

Woodman testimony, February 19, 1992 p. 24-25. Dr. Sherman conceded on cross-examination that she had in fact given that testimony. Sherman T. 171. It appears to this Court from this and other examples that Dr. Sherman will give whatever testimony may be convenient in any particular case.

58. For example, Dr. Sherman examined three Plaintiffs on April 23, 1992. On June 18, 1992, Defendants moved to preclude Dr. Sherman from testifying at trial

with respect to these physical examinations because they were performed in violation of this Court's June 4, 1991 Scheduling Order and after this Court's April 10, 1992 Order denying Dr. Sherman permission to perform late examinations. On July 2, 1992, in response to Defendants' motion to preclude her testimony concerning her examinations of Andre Williams, Bessie Cunningham, and Amber Burrell, counsel for Plaintiffs represented to the Court that they had no knowledge of this Court's April 10th Order at the time Dr. Sherman performed her examinations. Plaintiffs correctly noted that this Court's Order was actually entered on April 24, 1992. Specifically, they represented in their papers:

> In reliance upon defendants' proposed [alternative] deadline, *plaintiffs arranged to have Dr. Sherman complete her examinations on April 23, 1992* . . .
>
> Plaintiffs could not and did not learn of this Court's Order precluding medical examinations until *after it was entered on April 24, 1992.*

Plaintiffs' Memo. at 2-3 (emphasis supplied). Dr. Sherman, however, testified under oath that she limited her April 23 examinations to three Plaintiffs because the Plaintiffs had not yet received the Order. Dr. Sherman testified, "My understanding is that *the Court* had said that I could not examine these people." Sherman T. 154 (emphasis supplied). "[*S*]*ince there was a forbiddance of seeing everybody*, I think we tried to get one child, one woman and one man." Sherman T. 163 (emphasis supplied). She also claimed that she refrained from ordering conventional blood tests or other laboratory tests for Plaintiffs because of the April 10th order. Yet, Dr. Sherman had both completed her examinations of Williams, Cunningham, and Burrell and ordered the AAL tests *before* she had any knowledge of the Court's Order. In addition, Dr. Sherman had more than a year to examine the Plaintiffs before their Rule 26(b)(4) Statement was due on March 17, 1992. Sherman T. 142-43.

59. It was clearly Dr. Sherman's decision, not the Court's order, that caused her to refrain from performing other examinations or ordering additional lab tests.

60. As to the three Plaintiffs Dr. Sherman did examine, she claims to have made her own differential diagnosis in reaching the opinion that PCBs caused their various adverse health effects. Sherman T. 116-18. Even though Dr. Sherman's written medical reports for these three Plaintiffs did not contain a differential diagnosis, she asserts that she excluded alternative causes in her head. Sherman T. 120-21. However, at her deposition she testified under oath that she did not consider any alternative causes for Andre Williams' episcleritis. Sherman Dep. 679. Dr. Sherman's inconsistent testimony leads this Court to find her not credible as a witness.

61. It is apparent that in every one of her "diagnoses" Dr. Sherman did not consider and rule out alternative causes for the Plaintiffs' conditions—even though all of the Plaintiffs exhibit characteristics (*e.g.*, family history of disease, obesity, smoking, etc.) which, as Dr. Sherman also concedes, are known to cause the various injuries they allege. For each of these relatively common conditions there are numerous causes more generally agreed upon and accepted by the scientific medical community than Dr. Sherman's theories on PCBs. Weitekamp T. 65.

62. An example of Dr. Sherman's unscientific methodology can best set forth quoting directly from her deposition, Sherman Dep. 43,

> Q. Have you ruled out any causes of asthma other exposure to transformer fluid in the case of Patricia Ingram?
>
> A. No.
>
> Q. You have not done that?
>
> A. That's what I just said.

Again at Sherman Dep. 439,

> Q. Do you know of any support in the literature, Doctor, for the proposition that exposure to PCBs causes asthma?
>
> A. Yes.
>
> Q. What is that?
>
> A. I already quoted it to you, that was the Battleboro article.
>
> Q. Do you have that article with you Doctor?
>
> A. No.

* * * *

Again at Sherman Dep. 440,

> Q. Could you spell the author?
>
> A. B-A-T-T-L-E-B-O-R-O.

That questioning took place May 20, 1992. During Dr. Sherman's deposition on June 19, 1992, the questioner, Mr. Cox, returned to the subject as follows on page 99:

> Q. You identified a study by Battleboro or a reference by Battleboro as supporting your contention that PCBs were found to be associated with asthma. Do you have that study with you today?
>
> A. I'm glad you asked me. Yes I brought it. Yes I brought in Battleboro. I beg your pardon, it refers to the Battleboro[*sic*] Press.

* * * *

Again at Sherman Dep. 996,

> Q. Dr. Sherman, you were referring at some point to what you call the Battleboro article and you produced a two page article which appears to be a newspaper article which has now been marked as Sherman 55. What is that article?
>
> A. This is from Battleboro, Vermont by a patient who contacted me after becoming ill from leaking PCB containing oils in his submersible pump.

As it turned out, the Battleboro article which Dr. Sherman referred to as associating PCBs with asthma was nothing more than a newspaper report containing the claim by an individual that he got asthma because of PCBs in his drinking water. The article indicated that the case had been dismissed from court. Dr. Sherman never met the individual named in the article and she knew nothing about his medical history. That was the basis for Dr. Sherman's assertion that PCBs have been associated with asthma. Sherman Dep. 996-99.

63. As Dr. Fink testified, and as any lay person would known, a newspaper article cannot be relied upon as support for a medical diagnosis. Fink T. 47.

64. To support her opinion on medical causation, Dr. Sherman heavily relies upon the results of immunological tests from a "Chemical Injury Kit" administered by AAL. Even though she concedes that she is not an expert in immunology, Sherman T. 137, Sherman Dep. 229-30, Dr. Sherman nonetheless purports to use this data to reach the conclusion that PCBs have caused or will cause myriad adverse health effects in Plaintiffs, including cancer. Fink T. 28.

65. Dr. Sherman selected AAL, an unaccredited facility, Harbeck T. 84-85, as the lab to analyze the Plaintiffs' blood samples because of her prior experiences with the laboratory. Sherman T. 151. Dr. Sherman chose not to use a lab from the Philadelphia area for this testing. Sherman T. 151-52.

66. Dr. Phillips and Dr. Harbeck testified that the tests performed by AAL: (1) are unreliable; (2) do not allow a scientifically acceptable procedure or methodology; and (3) include tests that are not accepted in the medical or scientific communities. The evidence and testimony presented in support of Defendants' motion *in limine* to exclude this data is not disputed. Plaintiffs produced *no* evidence and *no* witnesses to rebut that testimony. Although Dr. Sherman herself selected AAL, she pro-

vided no testimony in opposition to Defendants' evidence regarding that lab. In fact, throughout her entire direct examination conducted by Plaintiffs' counsel, Dr. Sherman did not once mention the testing by AAL or address any issues raised by Drs. Phillips and Harbeck concerning the testing procedures, methodology or results reported by AAL. Sherman T. 91-132.

67. Defendants served a subpoena upon AAL compelling the production of 35 categories of documents pertaining to AAL's laboratory procedures and methodology, quality control, chain of custody of the blood samples, and analysis of blood samples which had been drawn from ten of the Plaintiffs and submitted to AAL at the direction of Dr. Sherman. The documents produced by AAL in response to this subpoena were entered into evidence without objection by Plaintiffs' counsel.

68. Prior to testifying at the hearing on the motion *in limine*, Dr. Phillips reviewed the laboratory findings primarily from AAL, the documents which were provided by Dr. Broughton, the deposition testimony of Dr. Sherman and some additional medical literature. Phillips T. 9.

69. In response to Defendants' subpoena, AAL failed to produce any records regarding:

(a) The dose-response curves for its tests, Phillips T. 29;

(b) Data regarding the use of current control groups to check the validity of the reported test results, Phillips T. 32;

(c) Quality control data used to ensure the validity of the testing, Phillips T. 37;

(d) Any documentation regarding when the blood samples were drawn, Harbeck T. 80-81; or

(e) The chain of custody regarding the Plaintiffs' blood samples, Harbeck T. 81.

70. Dr. Sherman testified that she has no personal knowledge regarding the circumstances under which the blood samples were drawn for AAL, when the blood samples were drawn, or when the blood samples were sent to AAL for analysis. Sherman T. 156.

71. Dr. Phillips testified that in the absence of clinical correlation, immunological tests are not "biologically relevant" or meaningful to the clinical evaluation of a patient. Phillips T. 10. In fact, "they probably would be more misleading and dangerous than helpful." Phillips T. 10. Dr. Phillips further testified that the presence of an abnormal test result on the types of test performed by AAL does not establish the presence of a disease and it does not establish a causual relationship between a disease and the cause of the disease. Phillips T. 11.

72. Dr. Phillips explained that there are numerous confounding factors that may produce positive results in the type of tests performed by AAL: "[I]f for example a patient is under stress, psychological or physical stress. If the patient has been drinking alcohol. If the patient has been using certain drugs. If the patient hasn't had enough sleep. If the patient has had a recent infection . . . ." Phillips T. 121. Indeed, "exposure to the sun can do this as well." *Id.*

73. It is undisputed that many of the tests performed by AAL have no clinical significance whatsoever and would not be performed by a reputable laboratory. For example:

(a) Dr. Phillips testified that the anti-brush border antibody test performed by AAL was totally inappropriate. "No reputable labortaory has measured this, except for research purposes . . . . [I]t has no clinical significance." Phillips T. 17.

(b) Dr. Phillips testified that the antimyelin antibody test performed by AAL "is of absolutely no biological meaning. It's a useless test." Phillips T. 17-18. This test

is of value only if it is used to test "the cerebral spinal fluid that is in the brain . . . . It has no meaning in the peripheral blood." Phillips T. 17. In the present matter, only blood samples were sent to AAL for analysis; not samples of spinal fluid. Phillips T. 18.

(c) Dr. Phillips also testified that the TA-1 test performed by AAL "is not done at most reputable laboratories . . . . [T]his particular antibody is not standardized [and the test] is not done in reputable laboratories which are certified to do these types of tests." Phillips T. 19-20.

(d) Further, Dr. Phillips stated that the PHA and the concanavalin A tests performed by AAL "are considered to be research only. The biological significance is not known." Phillips T. 20-21.

74. It is undisputed that the methodologies utilized by AAL to perform its testing are not scientifically valid. Harbeck T. 76. For example:

(a) AAL does not utilize dose-response curves to determine if they are using the proper type and amount of reagent in preparing the samples for analysis. Instead, "they arbitrarily pick . . . one dilution of reagent . . . ." Phillips T. 28-29. By not having "the dose response curve to illustrate the reactions . . . [the] tests are meaningless." Phillips T. 29.

(b) The AAL reporting of anti-nuclear antibody results merely as positive or negative is improper. Dr. Phillips testified that "depending on the test it's on, you can't simply say positive or negative, because it doesn't have any meaning." Phillips T. 30.

(c) AAL failed to provide any evidence regarding the use of proper control groups for the test results. Therefore, when AAL reports that a test was positive "it's meaningless." Phillips T. 32.

(d) In order to conduct its cell counting tests for T cells, AAL manually counts approximately 100 cells by

using a microscope. This method is out-dated and is not accepted in the scientific community and it is no longer used. Harbeck T. 82; Phillips T. 35. The manual method utilized by AAL is "not done anymore. It's notoriously inaccurate." Phillips T. 35. Instead, all reputable laboratories utilizes fluorescence activated cell sorting (FACS), which counts a minimum of 10,000 cells and has an accuracy of 99 percent. Phillips T. 32-35. There are laboratories in the Philadelphia area which utilize the FACS technology. Phillips T. 36.

(e) AAL does not "have quality control. They don't send their results out to a third party group or take reference standards from a third party group to allow them to assure that they have standard controls." Phillips T. 37.

(f) AAL does not identity the source of the reagents used in its testing. "[A]ny accredited, reputable laboratory would have the source of where you get these reagents. . . . [T]here's no evidence of where these were obtained, nor at what concentration . . . that they were used at." Harbeck T. 77. The source of the human serum used as the reagent is "a critical aspect of these sorts of experiments." Harbeck T. 78.

(g) The written procedures provided by AAL are "totally inadequate." Harbeck T. 79, 84.

(h) The tests performed by AAL need to be done within 24 hours after the blood is drawn. If the test is not conducted within this timeframe, "then there's a real problem with it." Harbeck T. 80. AAL provided no documentation as to when the blood samples were drawn. Harback T. 80-81.

75. The test results reported by AAL for the Plaintiffs' blood samples showed no pattern of similar response and there is no consistency among the results. Phillips T. 39-40.

76. AAL is not accredited by the College of American Pathologists ("CAP"). Harbeck T. 84-85. Accreditation by CAP ensures that the lab is "scrutinized by an on-site visit of peers who look at every aspect of laboratory operations, including quality control, sample acquisition, sample processing, reporting of results, instrument maintenance, external proficiency testing where you share your samples with other laboratories . . . ." Harbeck T. 85. By not undergoing accreditation, AAL avoids this type of scrutiny. Harbeck T. 86.

77. It is undisputed that the testing performed by AAL is not scientifically valid, that the tests are not accepted by the medical or the scientific communities as a means for measuring possible immunological effects of chemical exposure, that the methodologies and procedures utilized by AAL in performing the tests are not accepted in the scientific or medical community, and that the tests are of no clinical significance and would not be performed by a reputable laboratory. Phillips T. 17-21, 27, 41; Harbeck T. 76, 79, 84.

78. The AAL data is not data of the type reasonably relied upon in the medical profession. Fink T. 36; Weitekamp T. 67-68, 71; Phillips T. 17-21, 27, 35, 41; Harbeck T. 76, 79, 84. These experts explain that no competent expert in the fields of immunology, toxicology, or internal medicine would rely upon one set of immunological data—particularly data that are, as discussed above, totally unreliable—to offer the type of far-reaching conclusions that Dr. Sherman does. They point out that these immunological tests are not and cannot be relied upon by experts in the field to demonstrate "cellular damage," as Dr. Sherman claims. Fink T. 35-36, 38-39. And, they note that many of the specific immune parameters that Dr. Sherman insists are indicative of disease are in fact regularly present in individuals with no clinical manifestations of disease whatsoever. Phillips T. 10-11. They unequivocally attest that no expert in the field would

ever rely on these tests to diagnose an increased risk of cancer, as Dr. Sherman does. Thus, Dr. Sherman uses unreliable test results in a manner not recognized as acceptable by experts in any field of clinical medicine.

79. Dr. S. Michael Phillips, who is a professor of medicine at the University of Pennsylvania in the Allergy and Immunology Section and board-certified in internal medicine, allergy and immunology, testified that these tests "would not have been performed by a reputable immunologist for medical reasons." Phillips T. 17-21. Dr. Phillips also points out that the tests are unjustified, inappropriate, and invalid; that they mislead less sophisticated physicians and patients into believing that nonexistent immunologic abnormalities actually exist; and that no credibility should be accorded to such misleading and potentially dangerous findings. Phillips T. 10-11.

80. Drs. Fink, Phillips and Harbeck also have reviewed the protocol followed by AAL in performing the immune tests on which Dr. Sherman so heavily relies. They find serious flaws in the lab's method, and conclude that the results obtained from the "Chemical Injury Kit" are totally unreliable. Fink T. 44, 46; Harbeck T. 76; Phillips T. 41. For example, the lab often did not have control data, and several of the immune tests were not titered, making it scientifically impossible to rely on or determine the significance of the test results. Fink T. 44-45; Phillips T. 28-29.

CONCLUSIONS OF LAW

1. The hearings held by this Court on Defendants' motion *in limine* on July 28, 29, 30, 31 and August 3, 1992 have produced a record sufficient to evaluate Dr. Sherman's testimony under Rules 702, 703, and 403. In particular, the Court has made "a factual inquiry and finding as to what data experts in the field find reliable" (Rule 703) and created "a developed record and specific findings on reliabiltiy issues" (Rule 702). *In re Japanese Electronic Products Antitrust Litigation,* 723 F.2d 238,

277 (3d Cir. 1983); *rev'd on other grounds sub nom. Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986); *In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829, 859 (3d Cir. 1990), *cert. denied sub nom. General Elec. Co. v. Knight*, 111 S. Ct. 1524 (1991).

2. Rule 702 provides: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." Fed. R. Evid. 702.

3. "Rule 702 authorizes the admission of expert testimony so long as it is rendered by a qualified expert." *DeLuca v. Merrill Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 954 (3d Cir. 1990). If an expert is unqualified to offer the opinions she proposes, her testimony must be excluded from the trial. *Hines v. Consolidated Rail Corp.*, 926 F.2d 262, 272 (3d Cir. 1991); *see also Tokio Marine and Fire Ins. Co. v. Grove Manufacturing Co.*, 958 F.2d 1169, 1173-75 (1st Cir. 1992) (upholding exclusion of expert who was a "professional witness" and whose "opinions are available to the highest bidder as unqualified under Rule 702".)

4. Although Dr. Sherman received her medical degree in 1964, she did not complete a three-year residency program and has not diagnosed, treated or cared for individuals on an ongoing medical basis for the past 16 years. Findings of Fact ("FF") ¶¶ 1, 2. Since 1976, substantially all of the income Dr. Sherman generates is from her work in cases that involve litigation. She has participated in over 8,000 cases and has given depositions over 800 times. Dr. Sherman could not remember a single instance in which she examined an individual supposedly exposed to PCBs where she concluded that PCBs had not caused adverse health effects. FF ¶ 3. She has not had admitting privileges to any hospital since 1976 and does not maintain an office at which she can examine

patients. FF ¶¶ 4, 5. Dr. Sherman offers herself as an expert in internal medicine and toxicology and admits that she is not an expert in immunology, oncology, neurology, psychiatry, dermatology, epidemiology and exposure assessment. FF ¶ 6. She is not board-certified in any medical discipline. FF ¶ 7. Dr. Sherman contends that she became an expert in toxicology in the 1980s through experience, reading, writing, teaching, evaluating patients and course work. She took no toxicology courses in medical school and her training does not indicate that she is an expert in that discipline. FF ¶ 9. Dr. Jordan Fink, was called by Defendants and his qualifications appear at Factual Findings, paragraph 10. Dr. Fink testified that Dr. Sherman is unqualified to offer expert testimony in the fields of internal medicine for immunology. Dr. Fink recounted numerous errors in basic medical terminology and principles made by Dr. Sherman and concluded that these fundamental errors indicated Dr. Sherman's lack of qualifications. FF ¶ 11. He indicated further that Dr. Sherman's own testimony shows that she does not understand the functioning of the immune system; does not understand the immune tests that she ordered and purported to rely upon and that she is not qualified to interpret those tests. FF ¶ 11.

5. The defense called Dr. Paul Roediger as an expert and his qualifications are set forth in Factual Findings, paragraph 12. He testified that Dr. Sherman is not qualified as an expert in internal medicine, toxicology or immunology. He testified that Dr. Sherman would not receive admitting privileges at Abington Memorial Hospital and that the standards at Abington for granting privileges were similar to those employed in most hospitals in the country. He agreed with Dr. Fink's testimony with reference to Dr. Sherman's ignorance of the basic principles of internal medicine. FF ¶ 13.

6. Defense called Dr. James Leyden whose qualifications appear in the Factual Findings at paragraph 14.

Dr. Leyden testified that Dr. Sherman was not an expert in dermatology and was not qualified to diagnose chloracne or any dermatologic condition. FF ¶ 15. Dr. Morgan was also called by the Defendants and his qualifications appear in the Factual Findings at paragraph 18. Dr. Morgan testiefid that Dr. Sherman "does not have the qualifications that one would normally expect of an internist," and that she was also not qualified in the field of occupational medicine. He also noted that she had not practiced medicine for 16 years and cited several errors in basic anatomy and immunology that Dr. Sherman made in her deposition. FF ¶ 18. Dr. Weitekamp was called as a defense witness and his qualifications appear in the Factual Findings at paragraph 19. He also noted many errors made by Dr. Sherman with regard to basic principles of internal medicine and immunology and that she was unqualified in the fields of internal medicine and immunology. FF ¶ 19.

7. I find on the basis of the foregoing that Dr. Sherman is not qualified to testify as an expert witness at trial and that her testimony must be excluded under Rule 702.

8. In *United States v. Downing*, 753 F.2d 1224 (3d Cir. 1985), the Court said "Rule 702's helpfulness requirement implicitly contains the proposition that expert testimony that is based on unreliable methodology is unhelpful and therefore excludable."

9. All of the doctors who reviewed Dr. Sherman's testimony found that she failed to follow medically or scientifically reliable methodology in reaching her opinions in this case. *See* as to Dr. Fink, FF ¶ 11; as to Dr. Roediger, FF ¶ 13; as to Dr. Leyden, FF ¶ 15; as to Dr. Harbeck, FF ¶ 17, as to Dr. Morgan, FF ¶ 18; as to Dr. Weitekamp, FF ¶ 19, as to Dr. Phillips, FF ¶ 20. According to these witness who are all highly qualified in their respective fields, she did not order standard laboratory tests to be performed on Plaintiffs; she did not physically examine or take medically histories from most of the

Plaintiffs for whom she offered opinions; and as to the three Plaintiffs she did examine, she did so at the Plaintiffs' attorneys' offices and not in a medical office or hospital.

10. Drs. Fink, Roediger, Weitekamp and Morgan testified that a differential diagnosis—where the physician either rules in or rules out alternative causes for diseases—is the hallmark of internal medicine. According to Dr. Fink considering alternative causes is "the basic practice of internal medicine. That's what the internist does, make a diagnosis by taking the entire picture, outlining what the possibilities [are] and then honing down based on his knowledge and experience and literature that he has read, etc., in making a diagnosis." FF ¶ 54. Dr. Sherman does not follow this procedure, she assigns PCBs as the cause of the disease and does not consider and rule out any alternative causes. *See* FF ¶ 55 for a list of illnesses she attributes to PCBs; *see also* FF ¶ 62 for an example of Dr. Sherman's failure to rule out other causes of disease.

11. A shocking example of Dr. Sherman's methodology is set forth on pages 685 and 686 of her deposition. Bear in mind before you read this that Dr. Leyden, who has been described as one of the four or five most prominent dermatologists in the country, has testified that he can tell the difference between chloracne and common acne at fifty paces. FF ¶¶ 14, 15. I single out this particular testimony not only to illustrate that Dr. Sherman does not know the difference between the two types of acne, but more importantly to illustrate the methodology she used throughout all of her testimony:

Q. Have you ever seen chloracne?

A. Yes.

Q. Could you describe it for me?

A. It looks like your standard so-called teenage acne.

Q. Does it differ in any way from standard teenage acne?

A. Well, see, I'm glad you asked that question because how much of—how much of, quote, standard teenage acne is really chloracne that was never diagnosed correctly. Let's say you are a 15-year old boy living at Paoli, and you come to me because you have got acne on your face. And I say to you, oh, gee, there, Mr. Vardaman—well, I wouldn't call you Mr. Vardaman—you had better stop eating chocolate, and you had better wash your face with this kind of thing. But if I don't know that you lived at Paoli and I don't know that you have been exposed to PCBs, I may just say that you have got ordinary acne. Most of the acne cases have never been tested for PCBs.

Q. So, what is your answer? Can you differentiate chloracne from adolescent acne?

A. Yes.

Q. How do you do that?

A. You take a history.

Q. Is there any way, other than taking a history?

A. Yes.

Q. How?

A. Measure the soil. You measure for PCBs. You measure for dioxins. You measure for furans.

Q. Is there any way by simple looking at the patient and distinguishing between ordinary teenage acne and chloracne?

A. Well, we don't know whether ordinary teenage acne isn't really chloracne. You see, without a history, you don't know.

Could we stop to go to the loo for a minute.

12. I find that Dr. Sherman's failure to consider alternative causes of the Plaintiffs' complaints renders her testimony scientifically unreliable and legally inadmissible.

13. I find that Dr. Sherman's methodology with regard to her recommendation concerning medical screening is equally unreliable in that they do not employ recognized scientific techniques. Weitekamp T. 70-71

14. Rule 703 provides:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Fed. R. Evid. 703. Thus, if an expert relies upon facts or data not otherwise admissible and not reasonably relied upon by experts in the relevant field, then the opinion must be excluded. *Japanese Electronics,* 723 F.2d at 277.

15. The testimony of Drs. Fink, Phillips, and Harbeck demonstrates that the data Dr. Sherman relies upon, mainly the immunological test results from a "Chemical Injury Kit" administered by an uncredited lab, were not of the type reasonably relied upon by experts in any field of medicine to form a medical opinion. As Dr. Fink's states, "Dr. Sherman's use and interpretation of these tests reflects a general deficit in her—fundamental understanding of medicine and immunology." Fink T. 37-38. *See also* Phillips T. 10 (where he states that the immunological tests are not important or meaningful in the clinical evaluation of a patient and "they probably would be more misleading and dangerous than helpful").

16. I find that Drs. Fink and Phillips are well qualified to testify as to what data experts in their fields rely upon to reach medical opinions.

17. Plaintiffs have presented no expert to testify that immune data such as that ordered by Dr. Sherman are relied upon by experts in the fields. Defendants' evidence is undisputed on this point.

18. After considering the testimony, I conclude that the AAL data is not of the type reasonably relied upon by experts in those fields to reach the type of conclusion reached by Dr. Sherman. For this reason, I find Dr. Sherman's testimony must be excluded under Rule 703.

19. In *United States v. Downing*, 753 F.2d at 1242, the Court stated even if proffered evidence satisfies Rule 702 the district court may decide nevertheless to invoke Rule 403 to exclude the evidence.

20. Rule 403 states: "Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403.

21. Although pretrial Rule 403 exclusions are infrequent, when the court has a record complete enough on the point at issue to be considered a virtual surrogate for a trial record, it may exclude the testimony under Rule 403. *Paoli*, 916 F.2d at 859-60.

22. Testimony should be excluded if it would overwhelm, confuse or mislead the jury. *DeLuca*, 911 F.2d at 951; *Downing*, 752 F.2d at 1237.

23. Dr. Sherman's methodology of literally attributing every complaint a party has to PCBs when there is an allegation that the party has been exposed to PCBs would cause the jury to attribute more probative value to her opinion than that to which it would be entitled.

24. Dr. Sherman's practice of simply concluding that PCBs are a cause of a particular complaint and giving no basis for her opinion places an unfair burden upon

the defense to prove that PCBs were in fact not the cause of the complaint. In effect, it requires the defense to perform the differential diagnoses that Dr. Sherman should have done before reaching her conclusion.

25. The dangers of "confusion of the issues, or misleading the jury," are enhanced greatly by the manner in which Dr. Sherman either answers or avoids answering questions on cross-examination. See for example, *Sherman* Dep. 179, where defense counsel attempted to have her answer a question as to whether the author of an article concluded that PCBs caused high blood pressure. See also *Sherman* Dep. 131-43, where defense counsel attempted to get her to state whether John Ingram's PCB level was higher than that of the average for the population in the Philadelphia area among those who had no known exposure to PCBs.

DISCUSSION

I have found that Dr. Sherman is not qualified as an expert under Rule 702. In so doing, I have considered the length of time that has passed since she graduated from medical school and completed her one-year rotating internship and the fact that she does not diagnose, treat or care for individuals on an ongoing medical basis. As a matter of fact, she has not done so for the past sixteen years. From 1976 to the present, the only patients that Dr. Sherman has seen have been seen in the context of litigation consultation. Since 1976, substantially all of the income that she generated from her professional activities has come from work in cases that involve litigation. She has given over 800 depositions during that period and in all but two of those cases her testimony has been for the plaintiffs or claimants. Dr. Sherman could remember only a single instance in which she examined an individual allegedly exposed to PCBs where she concluded that PCBs had not caused adverse health effects.

Dr. Sherman has not had admitting privileges to any hospital in the country since 1976 and has not office at which she examines patients. Although Dr. Sherman offers herself as an expert in internal medicine and toxicology, she took no courses in toxicology in medical school and her subsequent training does not indicate that she has gained expertise since that time. She has never been board-certified in any medical discipline including internal medicine.

Dr. Sherman claims to have been involved in research of toxicologic problems since she concluded her clinical practice. This would appear to be library research of current literature on the subject. I did not observe anything in Dr. Sherman's testimony that indicted this so-called research was of a serious nature.

The expert witnesses called by the Defendants were impressive by reason of their education, their experiences and training since their formal years of education and the positions that they have held and presently hold in the medical field. Dr. Fink, for example, testified that Dr. Sherman is not qualified, that she does not employ the basic principles of internal medicine and that she demonstrates a fundamental lack of knowledge. He indicated that she is absolutely not competent to analyze the immune tests that she ordered and that she doesn't know basic immunology. Dr. Roediger agreed with that analysis and in addition stated that she would not be eligible for staff privileges at Abington Memorail Hospital. Dr. Roediger supervises the quality control aspects of the medical care at Abington Memorial Hospital and is in charge of 54 internists. He indicated that he has been reviewing the work of internists and doctors at the hospital for 20 to 30 years.

Dr. Leyden indicates that she is not qualified in the field of dermatology and was severely critical of her methodology and her lack of knowledge with reference

to acne. Dr. Weitekamp who is Chief of Internal Medicine at the Hershey Medical Center stated that Dr. Sherman is not qualified and that she displayed a basic lack of knowledge.

For all of these reasons, I find that Dr. Sherman is not qualified to testify as an expert in this case.

I therefore issue the following Order:

IN THE UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

George Burrell, et al. v. *Septa, et al.*	No. 86-2235
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
John Narcise, et al. v. *Septa, et al.*	No. 87-1190
Andre Williams, v. *Septa, et al.*	No. 87-1258
Charles Stanbach, et al. v. *Septa, et al.*	No. 87-3227
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269

ORDER

AND NOW, this 21st day of Oct., 1992, based upon the foregoing Findings of Fact and Conclusions of Law, it is hereby ORDERED that Defendants' Motion *In Limine* to Exclude the Opinion Testimony of Janette D. Sherman, M.D. is GRANTED, and it is further ORDERED that Defendants' Motion *In Limine* to Exclude All Testimony Concerning Tests Performed at Antibody Assay Laboratories, Inc. is GRANTED.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
Judge

APPENDIX III-B

IN THE UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

Master Dockets No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

George Burrell, et al. v. *SEPTA, et al.*	No. 86-2235
John Ingram, et al. v. *SEPTA, et al.*	No. 86-7561
Andre Williams v. *SEPTA, et al.*	No. 87-1258
Matthew Cunningham, et al. v. *SEPTA, et al.*	No. 87-5269

MEMORANDUM

R.F. KELLY, J. October 21, 1992

MOTION IN LIMINE TO EXCLUDE TESTIMONY OF IAN C. T. NISBET, Ph.D.

This is a toxic tort case brought by individuals who maintain that they have developed various illnesses as a result of their alleged exposure to polychlorinated biphenyls ("PCBs") from having either worked in or lived adjacent to the Paoli Railyard in Paoli, Pennsylvania. PCBs were used for decades in the transformers of the Paoli railcars and were found in elevated levels in the air and soil at and around the Paoli Railyard. Plaintiffs filed their complaints beginning in 1986. On November 28, 1988, this Court granted Defendants' Joint Motion for Summary Judgment against all Plaintiffs on their personal

injury claims. On September 20, 1990, the Third Circuit reversed the award of summary judgment in favor of Defendants and remanded the case to this Court for further proceedings consistent with its opinion. In accordance with the Third Circuit opinion, this Court held hearings on July 28, 29, 31 and August 3 and 7, 1992 eliciting testimony and argument on the numerous motions *in limine* and dispositive motions filed in this action.

Defendants filed this Motion *In Limine* to Exclude the Testimony of Ian C.T. Nisbet, Ph.D. Plaintiffs offer Ian C.T. Nisbet, Ph.D. ("Dr. Nisbet") as an expert in assessing the exposure of Plaintiffs to PCBs. Defendants argue that the testimony of Dr. Nisbet must be excluded since his opinions are based upon an unreliable methodology, erroneous factual assumptions and data not reasonably relied upon by experts in the relevant fields of science. Defendants argue that Nisbet's testimony should be excluded pursuant to Rules 702, 703 and 403 of the Federal Rules of Evidence.

A hearing on this motion was conducted on July 29 and 30, 1992. All parties were permitted to present witnesses and exhibits in support of or in response to this motion. Dr. Nisbet opines that several of the Plaintiffs were exposed to sufficient levels of PCBs to lead to the conclusion that they would suffer adverse health effects as a result of their exposure to PCBs. Upon consideration of Defendants' Motion *In Limine* to Exclude the Testimony of Ian C.T. Nisbet, Ph.D., all response thereto, the hearing and deposition testimony presented to this Court, and all exhibits admitted into evidence at the hearing, this Court makes the following Findings of Fact and Conclusions of Law:

FINDINGS OF FACT

1. Defendants presented the testimony of John Whysner, M.D., Ph.D. ("Dr. Whysner") in support of its motion *in limine* to exclude the testimony of Dr. Nisbet.

July 30, 1992 Hearing Testimony of Dr. Whysner ("Whysner T."). Defendants also introduced into evidence at the hearing Dr. Whysner's curriculum vitae (Defendants' *in limine* Exhibit 20), Dr. Whysner's affidavit (Defendants' *in limine* Exhibits 21), and the sworn deposition testimony of Dr. Nisbet (Defendants' *in limine* Exhibit 22).

2. Dr. Whysner, a physician and scientist, received his M.D. and his Ph.D. in Biochemistry from the University of Southern California School of Medicine in 1970. Whysner T. 5. Dr. Whysner's formal training in toxicology began when he was an undergraduate at the University of Southern California where he researched biological toxins. *Id.* at 6.

3. After receiving his M.D. and Ph.D., Dr. Whysner served as a pediatric intern for one year and spent two years as a post-doctorate fellow at the National Institute of Child Health and Human Development. *Id.* at 8.

4. In the early 1970s, Dr. Whysner supervised various toxicology studies for the executive office of the President. The studies involved the investigation of new pharmaceuticals for the treatment of drug abuse and the toxicity of certain illegal substances used in drug abuse. *Id.* at 6.

5. In the mid-to-late 1970s, Dr. Whysner was hired by the Center for Disease Control, the Department of Housing and Urban Development, and the National Bureau of Standards to investigate the toxicology of lead-based paint. *Id.* He later worked for the United States government under contract with the National Institute on Drug Abuse doing pharmaceutical research. Under this contract, he served as a toxicologist in terms of evaluating adverse drug reactions for the various pharmaceuticals tested. *Id.* at 6-7.

6. In the 1980s, Dr. Whysner worked in the area of occupational and environmental health for Washington Occupational Health Associates, Inc. where he investi-

gated the toxicological aspects of various occupational and environmental exposures. *Id.* at 7.

7. Presently, Dr. Whysner splits his time between the American Health Foundation, a non-profit research organization, and Washington Occupational Health Associates, Inc. At the American Health Foundation, he is in the department of pathology and toxicology and is currently in charge of an international expert panel that is looking into certain issues regarding the mechanism of cancer and cancer risk assessment. He also serves as Executive Secretary for the environmental health and safety council. *Id.*

8. Dr. Whysner's experience with exposure assessment includes assessing the exposure of children to lead from eating paint and performing exposure assessments on various environmental and occupational problems specifically PCBs, dioxins, dibenzofurans, polyaromatic hydrocarbons, and many other metallic elements and compounds. *Id.* at 8.

9. Dr. Whysner was offered by Defendants at the *in limine* hearing as an expert in toxicology and exposure assessment. *Id.* Plaintiffs did not challenge Dr. Whysner's qualifications.

10. Dr. Whysner reviewed the following: the deposition testimony of Dr. Nisbet; data concerning tests of Plainitffs' PCB blood levels performed by American Medical Laboratories, Inc.; data comparing the reliability of American Medical Laboratories, Inc. to other labs; the 1987 federal study undertaken by the Agency for Toxic Substances and Disease Registry of the Paoli residents; other studies of persons living near sites containing PCBs; and literature related to background PCB exposure levels. *Id.* at 9.

11. At the *in limine* hearing, Plaintiffs presented the testimony of Dr. Nisbet. July 30, 1992 Hearing Testimony of Dr. Nisbet ("Nisbet T."). Plaintiffs also intro-

duced into evidence at the hearing Dr. Nisbet's curriculum vitate (Nisbet *in limine* Exhibit P-1), Dr. Nisbet's handwritten notes regarding his back-calculations (Nisbet *in limine* Exhibit P-2), and an article titled "Methylmercury Poisoning in Iraq" (Nisbet *in limine* Exhibit P-3).

12. Dr. Nisbet received his bachelor's degree in 1954 from the University of Cambridge in England. He received his master's degree and Ph.D. degree in 1958 from the University of Cambridge. Dr. Nisbet's Ph.D. was in Physics with a specialization in fluid mechanics. Nisbet T. 59.

13. Dr. Nisbet did post-doctoral work for two years at Cornell University and Massachusetts Institute of Technology. He also did three years of post-doctoral work at the University of Cambridge. *Id.* at 59-60.

14. After completing his education in 1963, Dr. Nisbet spent five years teaching at the University of Malaya. Dr. Nisbet came to the United States in 1968. Since 1968, he has worked exclusively in the environmental sciences focusing on the behavior of chemicals and the effects of chemicals on the environment. *Id.* at 60.

15. In the early 1970s, Dr. Nisbet applied his mathematical knowledge to the modeling of the way chemicals move in the environment which led to what is now called "exposure assessment." In the mid-1970s, his work expanded into what is now called "risk assessment" which is the calculation of the likely effects of toxic chemicals on the environment. *Id.* at 60-61.

16. Since the mid-1970s, Dr. Nisbet's work has been almost exclusively in the area of risk assessment through tracking the way chemicals move in the environment and assessing exposure to the chemicals using toxicological and epidemiological information to assess risks. *Id.* at 61.

17. In 1975, the EPA commissioned Dr. Nisbet to produce a "criteria document" which was designed to summarize and analyze the considerable body of human and animal studies about PCBs.

18. The Electrical Power Research Institute ("EPRI") commissioned Dr. Nisbet's organization to do a review of PCB literature. Whysner T. 55-56. Drs. Whysner and Chase, two of Defendants' experts in this case, worked as subcontractors to Dr. Nisbet's group.

19. In 1991, Dr. Nisbet was selected by the Agency for Toxic Substances and Disease Registry ("ATSDR") as one of three peer reviewers for the draft of ATSDR's toxicological profile on PCBs. Nisbet T. 109.

20. Over the past twelve months, approximately 40% of Dr. Nisbet's time was spent working on cases that were in litigation. *Id.* at 107. Approximately 60% of Dr. Nisbet's income was derived from litigation-related activities over the past twelve months. *Id.* at 108.

21. Dr. Nisbet considers himself an expert in analytical chemistry in the limited area of reading and interpreting gas chromatograms of chlorinated hydrocarbons including PCBs. *Id.* at 108-09. However, when he submitted comments regarding his review of the ATSDR draft in 1991, Dr. Nisbet stated that he was not a specialist in analytical chemistry. *Id.* at 111.

22. There are two main methods used in assessing exposure to PCBs or any other chemical. The first method involves the measuring of a particular chemical in blood or urine samples through a regular laboratory test. Whysner T. 9-10. The laboratory provides a reference range along with the lab results which is the normal range for people who have been tested and do not have any unusual exposure to the chemicals. *Id.* at 10. The other method is called "exposure assessment" and is utilized for chemicals in which there are no good measurements in the blood. This method involves looking at the amounts of the particular chemicals in the environment, using a modeling system to develop hypothetical ways in which people could become exposed to those chemicals and deriving the amount of the chemicals that could be absorbed into the body. *Id.* These types of calculations are

usually done for regulatory purposes and do not assess what the actual levels of exposures are but assess the upper bounds of potential future exposures. *Id.* at 10, 34-35.

23. Dr. Whysner testified that Dr. Nisbet did not follow either of these methodologies. "He did not use the method directly of assessing in the blood but relied upon recalculation of laboratory results that had been obtained." *Id.* at 10-11. Dr. Nisbet did not perform an exposure assessment in this case nor did he specifically quantify the intake of PCBs experienced by any of the Plaintiffs. *Id.* at 11. Moreover, Dr. Nisbet did not perform a risk assessment in this case. *Id.*

24. In assessing Plaintiffs' exposure to PCBs, Dr. Nisbet took into account the history of use of PCBs at the Paoli Rail Yard and his own knowledge of the history of use and disposal of PCBs in the United States and other similar environments since 1970. Nisbet T. 82.

25. Dr. Nisbet concluded that Plaintiffs' exposure to PCBs was greatest before 1986 and "probably greatest in the early 1980s or 1970s." *Id.* at 85. However, he stated that "quantitatively, I don't know how the exposure changed in the years prior to 1986." *Id.* at 86. Dr. Nisbet based his conclusion that exposure was greatest prior to 1986 on the following: Monsanto halted PCB sales to customers who employed PCBs in other than so-called "closed systems" in 1971; Monsanto began warning its customers who warned their customers about the potential harms associated with PCB contamination in the early to mid-1970s; the 1976 passage of the Toxic Substances Control Act ("TSCA"); the promulgation of stringent TSCA regulations governing disposal of PCBs; improved "housekeeping" measures taken by the defendant railroads including the 1980 adoption of spill prevention control plans applicable to the Paoli Railyard; and the mid-1980s emergency measure taken by EPA to reduce water run-off from the Paoli Railyard to Plaintiffs' homes. *Id.* at 82-86; Nisbet Dep. 68-69.

26. In forming his conclusions, Dr. Nisbet also took into account Plaintiffs' own statements regarding how they used the environment, and the fact that Plaintiffs learned about the contamination in 1986 and undertook steps to reduce their contact with PCBs. Nisbet T. 82-83.

27. Dr. Nisbet reviewed Plaintiffs' files which included medical records, employment records for the employees, responses to interrogatories, and responses to questionnaires from some of the Plaintiffs. Nisbet Dep. 24.

28. Dr. Nisbet also reviewed information on the levels of PCBs in Plaintiffs' blood including some chromatograms and he reviewed various documents pertaining to the soil contamination at the Paoli Railyard and surrounding area. *Id.* at 25, 29, 35.

29. Dr. Nisbet admitted that he had no information about: any Plaintiff's exposure to PCBs at any time prior to 1986; the levels of PCBs in the soil of the Paoli neighborhood throughout 1950s, 1960s, and 1970s; the amount of PCBs used or disposed at the Paoli Railyard; the amount of surface run-off from the Yard at any time; the quantity of PCBs in the surface run-off; or the amount of rainfall in the Paoli area for any time period. *Id.* at 49, 69, 139, 144; Nisbet T. 86, 120-22.

30. Based upon all the information that he reviewed, Dr. Nisbet formed the opinion that several of the Plaintiffs "were sufficiently exposed [to PCBs from the Paoli Railyard] . . . to lead to the expectation that they would suffer adverse health effects as a result of th[eir] exposure." March 16, 1992 Report of Dr. Nisbet at 2, 6 (Attached as Exhibit 12 to Defendants' *in limine* Exhibit 22) ("Nisbet Report").

31. Dr. Nisbet expressed his opinion regarding the following six Plaintiffs: Priscillia Burrell; Amber Burrell; Bessie Cunningham; Matthew Cunningham; Patricia Ingram; and Andre Williams. Nisbet Dep. 474-75.

32. Dr. Nisbet did not quantify any of Plaintiffs' intake of PCBs nor does he believe it can be done. Nisbet T. 120. Dr. Nisbet did not quantify the intake of furans or dioxins by any of Plaintiffs. "I have not made any attempt . . . to make a formal calculation of exposure . . . ." Dr. Nisbet maintains that he does not have enough information to make any such calculations. *Id.* He stated that "it's not possible to make a quantitative estimate of the way in which the Plaintiffs' exposure varied during the 1970s and 1980s." *Id.* at 86. Dr. Nisbet did not at any time request that Plaintiffs be tested for the presence of dioxins, furans or tetraphenyls in their blood or fat tissue. *Id.* at 143-44.

33. Dr. Nisbet has never performed PCB analyses on human blood samples or human tissue samples. *Id.* at 111.

34. Although Dr. Nisbet claims to be an expert in exposure assessment of toxic chemicals, Dr. Nisbet has had no formal training in toxicology or epidemiology. *Id.* at 61, 144.

35. Various Plaintiffs in this case had their blood tested for PCBs in 1986 and 1987 by American Medical Laboratories, Inc. ("AML") and National Medical Services ("NMS"). Whysner T. 11.

36. In 1988, Dr. Nisbet explicitly adopted the AML results when he stated in an affidavit to this Court that "I have reviewed data on PCB levels . . . generated by American Medical Laboratories, Inc. (AML) For 16 of the plaintiffs, the data reported by AML indicate[s] substantial exposure to PCBs . . . ." Affidavit of Dr. Nisbet dated August 16, 1988 at 10 (attached as Exhibit 2 to Defendants' *in limine* Exhibit 22) ("Nisbet Aff."). Dr. Nisbet never questioned the reliability of the AML results in his 1988 affidavit. Nisbet T. 113-14.

37. However, at his deposition in 1992, Dr. Nisbet stated that he no longer considered the AML results to be reliable. Nisbet Dep. 108-09.

38. One basis for this conclusion is Dr. Nisbet's comparson of results from AML and Michigan State Laboratory obtained on the same three samples ("split samples") in March of 1986. Dr. Nisbet testified that AML's reported results were approximately two and a half to three times lower than Michigan State Laboratory's results. *Id.* at 158-60; Nisbet T. 80. During his deposition, he stated that he considered the Michigan State Laboratory to be more reliable than AML or that it was more reliable than AML at that time because he had independent knowledge of the Michigan State Laboratory. Nisbet Dep. 108. Based upon this belief and the 1986 lack of comparison between AML's results and the Michigan State Laboratory's results, Dr. Nisbet believed that the numbers reported by AML were "wrong, almost certainly wrong by a substantial factor" and that AML's results would generally be approximately two and a half to three times too low. *Id.* at 158, 164-68.

39. Applying this theory, Dr. Nisbet recalculated the results reported by AML in August of 1987 of Plaintiffs' PCB blood levels by multiplying these results by a factor of approximately two and a half to three yielding "recalibrated estimates." *Id.* at 159, 165 (emphasis added). Dr. Nisbet characterized his calculations at his deposition as follows:

> Q. And the method you used to do this recalculation is what?
>
> A. Simple multiplication.
>
> * * *
>
> Q. You used it only to give you some rough estimate, correct?
>
> A. That's correct.
>
> Q. Okay. But you think, as a scientist, that's an acceptable way to proceed, correct?
>
> A. If that's the only information you have, that's certainly acceptable.

Id. at 159, 178.

40. Dr. Whysner stated that there are a variety of reasons that could account for the difference in the 1986 split sample results of AML and Michigan State Laboratory. Whysner T. 14. One possible explanation is that something happened to the sample in transit to the laboratory or while the sample was stored. Another possibility is that one of the laboratories on that particular day was reading values on the high side and the other laboratory was reading on the low side. *Id.* at 14-15.

41. Dr. Whysner testified that it is common practice in the scientific community to contact the laboratory and request specific data regarding a sample testing if you think there are problems with the split sample results. *Id.* at 16-17. Dr. Whysner testified that "when I saw the deposition and the letter that Dr. Nisbet was relying upon, I called AML and asked them for any information they had about split samples or proficiency testing and I received it within a couple days." *Id.* at 16. Dr. Nisbet did not request this information from AML.

42. After seeing the data that Dr. Whysner referred to in his testimony, Dr. Nisbet admitted that the information showed better agreement between AML and the Michigan State Laboratory but he stated that the information showed disagreements between both of these labs and another lab. Nisbet T. 80. Dr. Nisbet went on to state that in order to place great weight on any of the blood sample results done by the various labs in 1986 or 1987, he would have to further review the information. *Id.*

43. Dr. Nisbet maintained that Plaintiffs' 1987 AML results are understated and unreliable for the following reasons: AML used an obsolete, low quality method; back-up data in the form of standards or quality control information, spikes, blanks, and surrogates was missing and unreviewable; a letter dated October 7, 1986 from SEPTA's counsel which stated in part that he lacked confidence in the PCB blood level results obtained from various labs in 1986 which included AML; lack of simi-

larity between the sample chromatogram and the chromatogram from the aroclor standard; some samples were not analyzed for approximately a month after they were collected; lack of information regarding how the samples were stored during that month in order to ascertain whether samples were kept under appropriate storage conditions; Plaintiffs' PCB blood levels as measured by AML in 1987 were comparable to the results recorded by Eco Logic in 1992 and Dr. Nisbet believed that the PCB blood levels should have dramatically decreased during this time period due to the half-lives; AML analyzed plasma not serum which Dr. Nisbet believes understates PCB levels; and the fact that the three split samples tested by AML in March of 1986 showed disagreement with the results from the Michigan State Laboratory. *Id.* at 73, 75-80, 101-02; Nisbet Dep. 106-07.

44. AML used the packed column method in analyzing Plaintiffs' blood samples in 1987. Nisbet T. 71.

45. There are two methods of analyzing PCBs. The first method is the capillary column method which separates the components of a PCB mixture. There may be 60 to 80 different PCB components which are called "congeners" in a human blood sample or an environmental PCB mixture. *Id.* at 69. The second method of analyzing PCBs is the packed column method. This is an older method which separates the congeners out into groups not the individual congeners. *Id.* at 70.

46. Dr. Nisbet testified that the capillary column method produces more information about the specific PCB congeners however more interpretation is needed. He stated that the packed column method is simpler, older, less expensive and a better known technique. *Id.* at 70, 72.

47. Dr. Nisbet testified that the AML data was unreliable because "the samples were not analyzed for more than a month after they were collected, as shown by the dates on the reports." *Id.* at 79. However, Dr. Nisbet

admitted at the hearing that the interval between the time the sample was collected and the time the results were repored was approximately two weeks. *Id.* at 117-18. Furthermore, the interval between the collection of blood samples and the 1992 report by ELI Eco Logic Laboratories, Inc. upon which Dr. Nisbet relied was in fact more than two months. *Id.* at 119.

48. Dr. Nesbit stated that the AML results were unreliable due to a potential problem that could exist regarding loss of changes in the blood samples during storage since he did not know "whether they were kept under appropriate storage conditions." *Id.* at 79. However, he admitted that he had no information that the 1987 AML samples were actually stored improperly. *Id.* at 119.

49. Another problem that Dr. Nisbet had with the 1987 AML results was that back-up data in the form of standards or quality control information was missing and unreviewable. He testified that he asked Plaintiffs' attorneys in 1990 or 1991 if the quality control data regarding the 1987 AML results could be obtained and was told that it did not exist. However, Dr. Nisbet conceded that he never requested the quality control data from the laboratory since he felt that labs generally don't keep that kind of information years after the tests. *Id.* at 115, 118; Nisbet Dep. 624.

50. This information was in fact available. Defendants obtained AML's back-up information regarding the 1987 blood results and supporting documentation and submitted it into evidence at the *in limine* hearing. Defendants' *in limine* Exhibit AML-1. This information included the following: AML's reports; lab certification documents; a description of AML's analytical method and its laboratory protocol for PCBs; redacted copies of the lab's logbook; chain-of-custody records for Plaintiffs' blood samples which set forth the circumstances of the shipment and handling of those samples; laboratory worksheets;

laboratory comparison data; descriptions of the credentials of AML laboratory analysts; and raw back-up data and instrument output for the samples, laboratory blanks, spiked samples, and standa ds. Defendants' *in limine* Exhibit AML-1. Dr. Nisbet did not review this information to supplement his earlier testimony.

51. Dr. Nisbet concluded that the error he believed existed in the March of 1986 AML results was still present at the laboratory in August of 1987. However, he admitted that the difference could have been greater or less than two and a half to three times by August of 1987. Nisbet Dep. 167-68. Furthermore, Dr. Nisbet could not identify the specific basis for his belief that AML's methods and procedures of analyzing PCBs in blood in August of 1987 were the same as in March of 1986. *Id.* at 168. Dr. Nisbet stated that he discussed this issue with Dr. Simon who was in charge of AML until some time around early 1986. However, Dr. Nisbet could not recollect much about his discussions with Dr. Simon. Mr. Vardaman, counsel for Defendants, asked Dr. Nisbet the following questions at his deposition:

> Q. I want to know, sir, did you have a discussion with Dr. Simon and he told you that the methodology that was being used in August of 1986, August of 1987, was the same as that was used in March of 1986?
>
> A. I'm sure I didn't discuss that specific month, but I recall having a discussion with Dr. Simon about the lab, and I feel confident that if there had been a change in methodology, he would have told me about that and placed a lot of weight on it.
>
> Q. Did you ask him?
>
> A. I don't remember.

Id. at 168-69.

52. Dr. Whysner stated that if "Dr. Nisbet had concerns about the reliability of the results reported by AML,

or any other laboratory, he could, and should, have requested inter-laboratory vertification data from the EPA and the laboratory." Affidavit of Dr. Whysner dated June 25, 1992 at 4 ("Whysner Aff."). Moreover, Dr. Whysner testified that there were other split sample tests and proficiency tests that were performed between March of 1986 and August of 1987 by AML. Whysner T. 15. In split sample testing, laboratories share samples and compare results. Proficiency testing involves the sending of a known sample to a laboratory and the laboratory reports the results. *Id.* Dr. Whysner testified regarding the availability of inter-laboratory comparison data that existed after March of 1986 which would have enabled Nisbet to confirm the reliabiltiy of the 1987 AML blood tests. First, in December of 1986, AML participated in the EPA proficiency testing program. As part of this program, EPA sent spiked samples to certain laboratories to determine the laboratories' accuracy in detecting known analytes. AML produced acceptable results in the EPA proficiency test. Second, in October of 1987, thirteen split samples taken from a group of Paoli Railyard workers were sent to both AML and Michigan State Laboratory and the reported results were very comparable for the two labs. Third, inter-laboratory exchanges of split samples in different cases between AML and Michigan State Laboratory in 1987 and again in 1989 demonstrated excellent comparability in PCB test results between the two labs. Fourth, Washington Occupational Health Associates, Inc. conducted its own proficiency testing beginning in 1986 which continued through 1992. As part of this testing, over 30 blood samples spiked with PCBs were sent to AML. The results of AML in this testing were almost identical to the spiked standard blood. The average result was only 5% higher than spiked samples. *Id.* at 15-16; Whysner Aff. 4-6.

53. In performing his recalculations of the 1987 AML results, Dr. Nisbet did not consider or refer to this inter-laboratory comparison data or the proficiency tests. Whysner T. 17.

54. Dr. Whysner testified that the 1987 AML results were very reliable. *Id.* He stated that it is not scientifically valid to take results obtained in 1986 from three split samples and use them to recalculate blood sample results obtained in 1987 as Dr. Nisbet has done in this case. *Id.* at 17-18. Dr. Whysner testified that as follows:

> I mean to take three samples, comparison samples between two laboratories that were done a year and a half before, and then essentially recalculate samples a year and a half later, is not proper. And there are many transient things [that] can happen in the laboratory at any particular time, and we have very good information regarding the comparability of AML's results with other laboratories within 1987, and in fact, very close to the time that AML took the plaintiffs blood or analyzed the plaintiff's blood.

Id. at 18-19. In all the years Dr. Whysner has been doing exposure assessments, he has never seen an expert use results from three split samples to recalculate results obtained from the same lab a year and half later. *Id.* at 19.

55. In addition to disputing the accuracy of the blood levels reported by AML, Dr. Nisbet also had a problem with the 5 to 30 parts per billion reference range used by AML in 1987 for normal/background exposure level of general population to PCBs. Nisbet T. 96. Dr. Nisbet stated that "the chart shows the same normal range of up to 30 parts per billion all the way from 1950 to 1990, and that's completely at variance of what we know about history of use, disposal, exposure of the general population to PCBs and the blood and fat levels." *Id.*

56. Dr. Whysner testified that the background levels used by AML were based upon over 15 studies which were reported in the literature and reports by various governmental agencies. These background levels represent levels of unexposed persons or persons without any known exposure to PCBs. Whysner T. 19.

57. Dr. Nisbet lowered the general population background PCB levels through the use of results obtained by the EPA in its National Human Adipose Tissue Survey ("NHATS"). Nisbet T. 96-99. NHATS was a study done by the EPA between 1970 and 1983 which analyzed fat samples not blood samples for the presence of PCBs in the general population. *Id.* at 97. NHATS measured the levels of PCBs in the fat samples in parts per million not parts per billion. *Id.* at 98.

58. Dr. Nisbet testified that NHATS showed a continuous and significant decrease in the number of individuals who had levels of PCBs greater than one between 1970 and 1983. *Id.* at 98-99. "A decrease is what you would expect, because levels in the human environment, particularly in human food have declined, which is documented." *Id.* at 99. Dr. Whysner testified that NHATS only reported the PCB fat levels in ranges because the agency did not believe that the data was accurate enough or reliable enough to come up with average levels in the fat tissue. Whysner T. 20.

59. Dr. Nisbet used the NHATS fat data to estimate the total amount of PCBs in the blood of the average person in the United States. Nisbet T. 142; Whysner T. 20-22. "He uses a calculation to estimate a lower level of background blood level using a partitioning coefficient which is a ratio of the amount of PCBs in the blood and amount of PCBs in the fat." Whysner 20-21. Dr. Whysner stated that he has never seen such a use of the NHATS fat data by experts in the field. *Id.* at 21. "I haven't seen it done to calculate blood levels for PCBs based upon fat levels in terms of trying to derive background levels before." *Id.* at 51.

60. The results of the 1987 AML blood tests which Plaintiffs ordered showed that Plaintiffs' PCB blood levels fell within the general population background PCB levels reported by the laboratory. *Id.* at 12, 21.

61. In essence, Dr. Nisbet takes two levels that are almost the same, Plaintiffs' 1987 PCB blood levels and the reported background levels, and recalculates Plaintiffs' PCB levels much higher and the background levels much lower. The result of these recalculations establishes a difference between the two levels. *Id.* at 21-22. Dr. Whysner characterized Dr. Nisbet's recalculations as "manipulating the data." *Id.* at 22.

62. Dr. Whysner stated that the November of 1987 ATSDR study of the Paoli residents found that there was no evidence of unusual exposure or uptake of PCBs in the Paoli residents. *Id.* at 29. The ATSDR study looked at PCB blood levels of people who had soil levels above 150 parts per million versus people who had soil levels below that level and found the blood levels to be virtually identical. *Id.* at 29, 42. The laboratory that analyzed the blood samples for the ATSDR study was the Center for Disease Control which is a United States government laboratory. Dr. Whysner stated that it was a very reputable laboratory. *Id.* at 56. In addition, Dr. Whysner testified that he analyzed the soil levels and bloods levels of Paoli residents who were nonoccupationally exposed and found no correlation between the soil levels in their residential yards and their blood levels. *Id.* at 42, 44. Furthermore, the AML blood tests and the ATSDR study are consistent with results of other governmental studies of persons living near sites containing PCBs that show no evidence of unusual exposure to PCBs. *Id.* at 30.

63. In 1992, six Plaintiffs' PCB blood levels were tested by ELI Eco Logic Laboratories, Inc. ("Eco Logic") of Canada. *Id.* at 22. The results of the Eco Logic data were very comparable to the results on the Plaintiffs obtained in 1986 and 1987 from AML and NMS. *Id.* at 22, 40-41. The 1992 blood tests "support the fact that the plaintiffs have exhibited general background levels over that period of time." *Id.* at 41.

64. Nevertheless, Dr. Nisbet again performed recalculations but this time of the Eco Logic data. *Id.*; Nisbet

T. 86. Dr. Nisbet estimated Plaintiffs' PCB blood levels as of 1986 based upon back-calculations of Plaintiffs' 1992 PCB blood levels recorded by Eco Logic. Nisbet T. 86-87, 102.

65. Dr. Nisbet assumed that Plaintiffs had high levels of PCB exposure prior to 1986. *Id.* at 86. Also, he stated that in 1986 the residents, including these Plaintiffs, took measures to reduce their own exposure. Dr. Nisbet testified that he attempted "to estimate to the degree possible, although not very quantitatively, but I attempted to estimate the range of possible magnitudes of [Plaintiffs' PCB] exposure, based on the most reliable set of data, which was the blood measurements taken in 1992." *Id.* at 86-87.

66. Dr. Whysner testified that the literature and studies do not support Dr. Nisbet's assumption of heavy prior PCB exposure by Plaintiffs above the normal background level. Whysner T. 29-30.

67. Dr. Nisbet utilized the 1992 Eco Logic PCB blood levels to perform a back-calculation of the concentration of specific congeners in the six Plaintiffs based upon various assumptions regarding the half-lives of the PCBs and a model for the back-calculation which incorporated different assumptions about the likelihood of continuing exposure from other sources. Nisbet T. 89-90, 124.

68. Dr. Nisbet projected Plaintiffs' possible "range" of PCB exposure as of 1986. Dr. Nisbet stated that the range was wide due to the fact that he projected back six years over several half-lives for a range of Plaintiffs' exposure to PCBs not a single number for the amount of exposure. *Id.* at 100-02.

69. First, in performing his back-calculations, Dr. Nisbet examined the Eco Logic results for the presence of certain congeners of aroclor 1260 in Plaintiffs' blood. Whysner T. 23. He took the values that are shown for these congeners and doubles these values based upon the

recovery rate of PCBs in the surrogate spike sample which was approximately 50%. (Dr. Whysner noted that Eco Logic did not double these values.) Dr. Nisbet used this recovery rate over the matrix spike sample recovery rate which was virtually 100%. (Dr. Nisbet testified that he was not aware of the matrix recoveries of the blood samples spiked with an aroclor mixture when he made his back-calculations. Nisbet T. 91.) Dr. Nisbet then multiplied the doubled congener values by eight based upon his concept of half-lives that one-half of the PCB congener will dissipate from an individual every two years. Next, he multiplied by "another factor in order to estimate the total amount of this aroclor 1260 based upon this one congener number." Finally, Dr. Nisbet divided these numbers by two since he believes that it is a complex mixture and some of the congeners would have been eliminated from the body. Whysner T. 23-27. "The net effect is to multiply [the congener values] by 16, and then divide [these values] by two and come up with a number." *Id.* at 27. Then end result of Dr. Nisbet's back-calculations is that he estimated that Plaintiffs' 1986 PCB blood levels were approximately eight times what their levels were in 1992. *Id.*

70. Dr. Whysner testified that Dr. Nisbet's back-calculation under these circumstances is not a recognized methodology. *Id.* at 31. "I have never seen [back-calculations] used in this kind of situation;" this is unprecedented and not valid. *Id.* As Dr. Whysner observed regarding the use of back-calculations in this context, "you could hypothesize for anybody that [their PCB levels] could have been much higher [than] the background in the past." *Id.* Dr. Whysner went on to state that "the major [problem with Dr. Nisbet's methodology] is that . . . you have to assume the thing that you are trying to prove in the first place." *Id.* at 28. First, Dr. Nisbet must assume that the results from AML and NMS and the ATSDR study are not valid. He also must assume a huge prior exposure and that exposure went way up

and then way down again. Dr. Whysner stated that these are not valid assumptions. *Id.* at 28-29. He testified that there is simply no evidence of such a significant exposure, and it is not scientifically valid for Dr. Nisbet to use back-calculations to prove such a prior exposure. *Id.* at 29-31. Dr. Nisbet's method is completely speculative. *Id.* at 31-32.

71. Dr. Nisbet testified that the Eco Logic data showed significant levels of PCBs in all six of the Plaintiffs that were tested in 1992. Dr. Nisbet stated that:

> [T]he total levels of PCBs adding all congeners together, varied between 6.7 and 27 parts per billion. Those in themselves are significant levels, particularly in 1992. . . . That's a very crude assessment. Adding it all together you lose nearly all of the information. That's what was wrong with the earlier analyses. My primary conclusions were the ones that I drew from the pattern of occurrenec of specific congeners. . . . [T]here were high levels of certain specific congeners that were characteristic of aroclor 1260 and to a lesser extent, some specific congeners that were very characteristic of aroclor 1254.

Nisbet T. 93.

72. In performing his back-calculations, Dr. Nisbet relied upon congeners 180, 194, 201, 205, 206, 138 and 118. Dr. Nisbet stated that he checked the chromatograms and the computer print-out from the confirmatory column to make sure that the congeners appeared on both capillary columns. *Id.* at 127. However, when asked to identify where congeners 180, 205, 206 and 118 appeared on the confirmatory column print-out, Dr. Nisbet failed to do so. *Id.* at 128-30. He later admitted that he tabulated the confirmatory results on his own by using the chromatograms not the computer print-out prepared by Eco Logic from its confirmation. He stated that he did not use Eco Logic's confirmation because he had not seen it at the time he did his own calculations. *Id.* at 129-30.

73. Dr. Nisbet testified that confirmation by the second column (DB17 column) in congener specific analyses is "pretty important, but it's not crucial, because its internal confirmation comes from the patterns of the currents of the different congeners." *Id.* at 126. He stated that we would use results that were unconfirmed by the DB17 column to evaluate PCB levels in humans but he would not place weight on a single congener without some kind of confirmation. *Id.*

74. Dr. Nisbet used alternative values for half-lives when making his calculations of Plaintiffs' 1986 ranges of exposure. The numbers he used were between one and six years for the various half-lives. *Id.* at 102. Dr. Nisbet stated the following reasons for using different half-lives: information on half-lives indicates that in the absence of any continuing exposure, the half-lives for the specific congeners is a little less than one year; he recognized that there may have been some continuing exposure of Plaintiffs, so he concluded that it was likely that the actual rate of depletion of the congeners from their blood would have been less rapid than a half-life of one year; and he used a range of values higher than one year after "spanning the values that have been reported in the literature for total PCBs to indicate the possible range that may have occurred in those people in 1986. And I drew semi-quantitative conclusions from those ranges, not from a single number." *Id.*

75. Dr. Nisbet stated that the Eco Logic results prove past exposure to the materials used at the Paoli Railyard specifically the aroclor 1260 that was used in some of the transformers. He also maintained that the patterns of the different congeners was not the same as that in aroclor 1260 because they had been highly weathered which shows that the main exposure of Plaintiffs to these congeners had taken place some time in the past. *Id.* at 94.

76. Dr. Nisbet further testified that the Eco Logic results showed that the degree of differentiation in some

of the congener specific analyses was greater in Plaintiffs than that reported of the general population. *Id.* at 95. However, Eco Logic failed to provide a reference range for its 1992 results. Eco Logic did not have information regarding the background levels of the various congeners in the general population. *Id.* at 124.

77. Dr. Nisbet stated that he was satisfied with the reliability of the Eco Logic data since he examined Eco Logic's reports, spoke to the principal scientists who supervised the work, Mr. Gierczak, to clarify various points, the protocol/procedure was reliable, the qualitative identification of the chromatograms for the two different capillary columns was good, and the quality assurance in the quality control data was good. *Id.* at 87-88.

78. Dr. Nisbet testified that if he had access to reliable PCB blood tests for Plaintiffs in 1986, then he would choose the results of these tests over his own estimates using back calculations. *Id.* at 138.

79. Dr. Nisbet stated that he did an exposure assessment for Plaintiffs in the very broad sense but not in the narrow sense. *Id.* at 143-44. Dr. Nisbet testified that he did not perform a risk assessment in this case. He did not project forward. *Id.* at 144.

80. Dr. Nisbet stated that his use of half-lives in this way has been used in the context of projecting back to earlier blood levels of drugs or alcohol. *Id.* at 103. "It's used on a limited basis in environmental situations. The question doesn't often arise in environmental situations for extrapolating backwards." *Id.* Dr. Nisbet gave an example of a study conducted by Toxicologists at the University of Rochester and the University of Baghdad. This was a study of a mercury poisoning epidemic in Iraq in the early 1970s. The study projected backwards from the blood levels of mercury observed in the poisoned people some time after they stopped ingesting the contaminated food to what the levels would have been earlier in the blood. *Id.* at 103-04. However, this study was not

used to determine whether there had been in fact exposure or exposure above the background levels since that was already known. This study was a dose response investigation. *Id.* at 134-36. The inter-university report stated that:

> Large errors may result if an average half-time is used to extrapolate mercury concentrations in blood back to the time of consumption of contaminated bread. Analyses of hair samples . . . give a more accurate recapitulation of exposure and therefore will be of much greater importance in epidemiological studies.

Nisbet *in limine* Exhibit P-3 at 234-35.

81. Dr. Nisbet also stated that he performed back-calculations before in a case involving a pest control operator who died of cancer. Dr. Nisbet took the levels of PCBs that were found in the operator's tissues at the time of death and projected them backwards using information regarding half-lives to estimate what the levels would have been in his blood when he was actively using the pesticides. Nisbet T. 125.

82. Dr. Nisbet gave another example of a study that used back calculations called the Ranch Hand study by the Center for Disease Control which researched Agent Orange veterans. *Id.* at 136. However, Dr. Nisbet subsequently admitted that he was not sure if the Ranch Hand study performed back calculations to estimate exposure or if he was referring to a commentary on the study by another scientist. *Id.* at 146.

CONCLUSIONS OF LAW

1. In cases involving proffers of scientific evidence, the Third Circuit stated that "[i]t would appear that the most efficient procedure that the district court can use in making the reliability determination is an *in limine* hearing." *United States v. Downing*, 753 F.2d 1224, 1241 (3d Cir. 1985). The court went on to state that "[i]n

the course of the *in limine* proceeding, the trial court may consider, *inter alia*, offers of proof, affidavits, stipulations, or learned treatises . . . in addition to testimonial or other documentary evidence (and, of course, legal argument)." *Id.*

2. This Court has before it a developed record and specific findings regarding reliability issues. *In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829, 858 (3d Cir. 1990), *cert. denied sub nom. General Elec. Co. v. Knight*, 111 S. Ct. 1524 (1991). This Court has made a factual inquiry and finding as to what data experts in the field find reliable. *In re Japanese Electronic Products Antitrust Litigation*, 723 F.2d 238, 277 (3d Cir. 1983), *rev'd on other grounds sub nom. Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986).

3. The hearings held by this Court on July 29 and 30, 1992 relating to Defendants' Motion *In Limine* to Exclude the Testimony of Dr. Nisbet have produced a sufficient record to evaluate Dr. Nisbet's testimony under Federal Rules of Evidence 702 and 703.

4. The district court has broad discretion to admit or exclude expert evidence. The court's action will be sustained unless "manifestly erroneous.' *Salem v. United States Lines Co.*, 370 U.S. 31, 35 (1962).

5. A district court's decision to exclude the testimony of an expert will be upheld absent an "abuse of discretion." *Knight v. Otis Elevator Co.*, 596 F.2d 84, 87 (3d Cir. 1979).

6. The Federal Rules of Evidence embody a strong preference for admitting evidence that has some potential of assisting the jury. *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 956 (3d Cir. 1990).

I. EXCLUSION BASED UPON RULE 702

7. Rule 702 of the Federal Rules of Evidence ("Rule 702") provides that:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702.

8. "Rule 702 authorizes the admission of expert testimony so long as it is rendered by a qualified expert and is helpful to the trier of fact." *DeLuca*, 911 F.2d at 954 (citations omitted).

9. There is a presumption of helpfulness given to expert testimony under Rule 702. *Japanese Electronic*, 723 F.2d at 279.

10. Rule 702's helpfulness requirement implicitly contains the proposition that expert testimony that is based upon unreliable methodology is unhelpful and thus excludable. *DeLuca*, 911 F.2d at 954.

11. The focus of the Rule 702 inquiry is on the reliability of the methodology employed by the expert in reaching his or her conclusions. *Paoli*, 916 F.2d at 856-57; *Downing*, 753 F.2d at 1238.

12. The Third Circuit in *Downing* established a more flexible approach to the admissibility of "novel" scientific evidence under Rule 702. 753 F.2d at 1237. *Downing* requires a district court to conduct a preliminary inquiry focusing on:

> (1) the soundness and reliability of the process or technique used in generating the evidence,
>
> (2) the possibility that admitting the evidence would overwhelm, confuse, or mislead the jury, and
>
> (3) the proffered connection between the scientific research or test result to be presented, and particular disputed factual issues in the case.

Id.

13. Novel scientific evidence includes scientific evidence that has not been generally accepted or well-recognized in the particular scientific community to which it belongs so as to warrant recognition by judicial notice. *Paoli*, 916 F.2d at 856 n.34; *Downing*, 753 F.2d at 1234, 1237.

14. The reliability inquiry is flexible. The court may examine a variety of factors in addition to scientific evidence in assessing reliability of a particular technique or methodology. *Downing*, 753 F.2d at 1238. For example, the court may examine the expert's technique in relation to more established modes of scientific analysis and the existence of specialized literature dealing with the expert's technique or methodology. "Both of these factors bear on the likelihood that the scientific basis of the new technique has been exposed to critical scientific scrutiny." *Id.* at 1238-39 (citations omitted). Other factors include: the non-judicial uses to which the scientific technique are put; the qualifications of the expert witness; and the frequency with which the methodology or technique leads to erroneous results. *Id.* at 1239.

15. If a reliable methodology was "so altered as to skew the methodology the methodology itself, *Downing* would be the appropriate vehicle for evaluation" but not if the challenged procedure was an application of an accepted methodology. *Paoli*, 916 F.2d at 858 (citing *DeLuca*, 911 F.2d at 955 n.15).

16. After assessing the reliability of an expert's methodology, the court must determine whether admitting the evidence would overwhelm, confuse or mislead the jury. *See DeLuca*, 911 F.2d at 957.

17. "This inquiry focuses on the extent to which probative scientific evidence is capable of being properly utilized by the jury . . . ." *Id.*

18. The touchstone of Rule 702 is the "helpfulness of the expert testimony, *i.e.*, whether it 'will assist the trier

of fact to understand the evidence or to determine a fact in issue.'" *Downing*, 753 F.2d at 1235 (quoting Fed. R. Evid. 702).

19. Helpfulness turns on whether the expert's methodology is sufficiently reliable so that it will aid the jury in reaching accurate conclusions. *DeLuca*, 911 F.2d at 956 (citation omitted).

20. An expert's opinions cannot rely on unsupported factual assumptions. "In order to testify as an expert under Fed. R. Evid. 702, a witness must be sufficiently qualified and expert testimony must be helpful to the fact finder by providing an adequate factual foundation." *Hines v. Consolidated Rail Corp.*, 926 F.2d 262, 272 (3d Cir. 1991) (citations omitted).

21. "An opinion based on false assumptions is unhelpful in aiding the jury in its search for the truth, and is likely to mislead and confuse." *Wilkinson v. Rosenthal & Co.*, 712 F. Supp. 474, 479 (E.D. Pa. 1989).

22. Where the record and factual findings demonstrate that the expert used an unreliable scientific mode of analysis and thus obtained "inaccurate results" from this analysis, the court must exclude the proffered testimony pursuant to Federal Rule of Evidence 702. *See Paoli*, 916 F.2d at 857.

23. Defendants in this case argue that the *Downing* test applies to Dr. Nisbet's methodology in recalculating Plaintiffs' 1987 AML results by a correction factor based upon three values obtained in a split sample test in 1986. Dr. Nisbet disputed the reliability of direct measurements of Plaintiffs' 1987 PCB blood levels and formulated his method of estimating those levels. Findings of Fact ("FF") ¶¶ 38, 39, 43. I conclude that this methodology is indeed novel since it was not performed in conformance with any known methodology and is not generally accepted in the scientific community. *See* FF ¶¶ 41, 42, 52-54.

24. Dr. Whysner testified that no reasonable scientist in the field of exposure assessment would recalculate laboratory results based upon three unconfirmed values from a split sample test obtained a year and a half earlier. FF ¶ 54. Moreover, Dr. Whysner testified as to the wealth of information available to Dr. Nisbet to properly evaluate the reliability of Plaintiffs' 1987 AML blood results. FF ¶¶ 49, 50, 52, 53. Dr. Whysner stated that it is standard procedure in the field of exposure assessment to contact a laboratory and review its procedures if you question the reliability of certain results. Dr. Nisbet failed to follow this practice. FF ¶ 41.

25. Dr. Nisbet has failed to identify any literature supporting his recalculation of the 1987 AML results nor has his methodology been endorsed by other experts in field of exposure assessment. Thus, there is no likelihood that Dr. Nisbet's methodology has been exposed to "critical scientific scrutiny." This factor weighs against admissibility. *See Downing*, 753 F.2d at 1238-39.

26. Dr. Nisbet based his opinion regarding the unreliability of the 1987 AML results on unsupported and false assumptions. First, Dr. Nisbet assumed that the 1986 AML results were two and a half to three times too low rather than that the Michigan State Laboratory results were two and a half to three times too high. Dr. Nisbet based this conclusion on his belief that the Michigan State Laboratory was "more reliable." FF ¶ 38. Dr. Whysner testified that it is common practice in the scientific community to contact the laboratory and request data regarding a sample testing if you think there is a problem with the split sample results. FF ¶ 41. Dr. Nisbet did not request this information. After seeing this information, Dr. Nisbet adopted an additional theory that both AML and Michigan State Laboratory could be unreliable. FF ¶ 42.

27. His next assumption was that AML's results would generally always be two and a half to three times too low.

FF ¶ 38. Dr. Nisbet failed to point to any evidence to support this assumption. Moreover, he concedes that he has no information that AML was in fact following the same procedures in August of 1987 as it did in March of 1986. FF ¶ 51.

28. Furthermore, Dr. Nisbet disregarded inter-laboratory comparison data and proficiency test results that were available after the 1986 split sample tests. This data would have enabled him to evaluate the 1987 AML results based upon data and results that were more substantial and information that was more recent regarding the conditions at AML and its comparison to Michigan State Laboratory in August of 1987. *See* FF ¶¶ 52, 53.

29. Dr. Nisbet also based his opinion that the 1987 AML results are unreliable on two erroneous factual assumptions. First, he stated that AML back-up data and quality control information was not available to evaluate the 1987 AML results. This information in fact was available and was admitted into evidence at the hearing. FF ¶¶ 49, 50. Second, Dr. Nisbet stated that the 1987 samples were stored for over a month and that the storage conditions may have affected the samples. These samples were in reality stored for approximately two weeks. FF ¶ 47. In addtion, Dr. Nisbet admitted that he had no information that the samples were stored improperly. FF ¶ 48.

30. I find that Dr. Nisbet's conclusion that Plaintiffs' 1987 AML results are unreliable is based upon unsupported factual assumptions and will not aid or assist the jury in reaching "accurate conclusions" under Rule 702. Furthermore, Dr. Nisbet's failure to review AML's quality control information, inter-laboratory comparison data and proficiency test results renders his testimony scientifically unreliable and legally inadmissible.

31. With regard to Dr. Nisbet's back-calculations, Plaintiffs and Defendants agree that the *Downing* test for novel scientific evidence is the appropriate standard to

review Dr. Nisbet's back-calculations of the 1992 Eco Logic results.

32. Dr. Nisbet estimated Plaintiffs' PCB blood levels as of 1986 based a recalculation of Plaintiffs' 1992 PCB blood levels recorded by Eco Logic. Dr. Nisbet assumes that Plaintiffs had high levels of PCB exposure prior to 1986. He attempted "to estimate the degree possible, although not very quantitatively, but I attempted to estimate the range of possible magnitudes of [Plaintiffs' PCB] exposure, based on the most reliable set of data, which was the blood measurements taken in 1992. FF ¶ 65.

33. Dr. Nisbet utilized the 1992 Eco Logic PCB blood levels to perform a back-calculation based upon various assumptions regarding the half-lives of the PCBs and likelihood of continuing exposure from other sources. FF ¶ 67. Dr. Nisbet projected Plaintiffs' possible "range" of PCB exposure as of 1986. FF ¶ 68.

34. Dr. Nisbet's back-calculation under these circumstances was not an application of a recognized methodology. FF ¶ 70. Dr. Whysner stated that "I have never seen [back-calculations] used in this kind of situation;" this is unprecedented and not valid. *Id.* Dr. Whysner went on to state that "the major [problem with Dr. Nisbet's methodology] is that . . . you have to assume the thing that you are trying to prove in the first place." *Id.*

35. I find that Dr. Nisbet's method of back-calculating Plaintiffs' 1992 PCB blood levels to 1986 presupposes exactly what he is trying to establish which is unusual prior exposure to PCBs by Plaintiffs.

36. Moreover, Dr. Nisbet's rough estimates of Plaintiffs' 1986 PCB blood levels through his back-calculations are completely speculative and likely to lead to erroneous results. These rough estimates of Plaintiffs' "potentials" for exposure will not aid or assist the jury under Rule 702.

37. Dr. Nisbet failed to cite any literature that supports his use of back-calculations when estimating unknown prior exposure to toxic chemicals in an environmental situation. *See* FF ¶¶ 80-82. Nor has this methodology been endorsed by other experts in field of exposure assessment. Thus, Dr. Nisbet's methodology has not been exposed to scientific scrutiny. Dr. Nisbet does not cite a single study that measures PCB blood levels directly without adjusting the laboratory results through his own calculations.

38. Dr. Nisbet failed to present any evidence that his recalculations of the 1987 AML data and his back-calculations of the 1992 Eco Logic data have been put to any "non-judicial use." *Downing,* 753 F.2d at 1239. This also weighs against the admissibility of his methodology.

39. I conclude that it is not scientifically valid for Dr. Nisbet to use back-calculations to prove Plaintiffs' prior exposure to PCBs under the circumstances of this case. Dr. Nisbet's back-calculations in this situation are unprecedented and unreliable, and must be excluded.

40. Dr. Nisbet's methodology regarding back-calculations was also found unreliable by the court in *Carroll v. Litton Systems, Inc.*, No. B-C-88-253, 1990 U.S. Dist. LEXIS 16833 (W.D.N.C. Oct. 29, 1990).[1] The court excluded the testimony of the plaintiffs' exposure expert who back-calculated the levels of plaintiffs' past exposure to trichloroethylene ("TCE") using estimated half-lives of the chemicals. The court in *Carroll* stated that the expert's "method of determining historical concentrations has no recognition, or even reference, in any scientific literature, in learned treatises, or in any actual application," and that half-lives are used prospectively only. *Id.* at *34.

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[1] *Carroll* was written by a United States Magistrate and was adopted by the district court by order dated July 15, 1991.

II. *EXCLUSION BASED UPON RULE 703*

41. Rule 703 of the Federal Rules of Evidence ("Rule 703") provides that:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Fed. R. Evid. 703.

42. Rule 702 deals with examining the method by which the data is analyzed while Rule 703 deals with examining the underlying data that an expert analyzes. *Paoli,* 916 F.2d at 856.

43. The proper inquiry is not what the court considers reliable, but what experts in the relevant discipline consider to be reliable. *Japanese Electronic,* 723 F.2d at 276 (citations omitted).

44. This Court has a "proper and reviewable foundation for making its admissibility findings," *Paoli,* 916 F.2d at 853, and has conducted the requisite factual inquiry under *Japanese Electronic* to determine what type of facts or data experts in the field of exposure assessment find reliable. 723 F.2d at 276.

45. I find that Dr. Whysner is well qualified to testify as to what facts or data experts in the field of exposure assessment rely upon to reach their conclusions. FF ¶¶ 2-9.

46. Dr. Nisbet recalculated Plaintiffs' 1987 AML blood results by inflating these results by a factor of two and a half to three. He arrived at his "correction factor" by comparing values obtained from three split samples in 1986 from AML and Michigan State Laboratory. FF ¶¶ 38, 39.

47. In all the years Dr. Whysner has been doing exposure assessments, he stated that he had never seen an expert use results from three split samples to recalculate results obtained from the same lab a year and a half later. FF ¶ 54.

48. I conclude that the 1986 data obtained from the three split samples and the "recalibrated" 1987 AML results based upon Dr. Nisbet's correction factor are not data of the type reasonably relied upon by experts in the field of exposure assessment as required under Rule 703. Thus, Dr. Nisbet's testimony that is based upon this data must be excluded.

49. Dr. Nisbet also lowered the general population background PCB blood levels by using results obtained in NHATS. This was a study which analyzed fat samples not blood samples for the presence of PCBs in the general population. FF ¶ 57. Dr. Whysner testified that NHATS reported PCB fat levels in ranges because the data was not accurate enough or reliable enough to arrive at the average PCB levels in the fat tissue. FF ¶ 58.

50. Dr. Nisbet used the NHATS fat data to estimate the total amount of PCBs in the blood of the average person in the United States. He estimated a lower background PCB blood level by using a partitioning coefficient which was a ratio of the amount of PCBs in the blood and amount of PCBs in the fat. FF ¶ 59.

51. Experts in the field of exposure assessment do not reasonably rely upon NHATS fat data to calculate background PCB blood levels. *Id.*

52. I conclude that Dr. Nisbet's recalculation of the background PCB blood levels through use of the NHATS fat data is not data of the type reasonably relied upon by exposure assessment experts. Accordingly, any testimony of Dr. Nisbet that relies upon this data must be excluded.

53. Defendants argue that Eco Logic's 1992 results should also be excluded pursuant to Rule 703. The 1992 Eco Logic results form the sole basis for Dr. Nisbet's back-calculations. I have concluded in another memorandum which addresses Defendants' Motion *In Limine* to Exclude Results of Analyses Performed by Eco Logic to exclude the Eco Logic data under Rule 703 since it is not of the type reasonably relied upon by experts in the field of exposure assessment. Thus, Dr. Nisbet's testimony concerning the 1992 Eco Logic results must be excluded under Rule 703.

For the foregoing reasons, I find that Dr. Nisbet is not qualified to testify as an expert in this case under Rules 702 and 703 of the Federal Rules of Evidence. Therefore, I shall enter the following order:

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master Docket No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

George Burrell, et al. v. *SEPTA, et al.*	No. 86-2235
John Ingram, et al. v. *SEPTA, et al.*	No. 86-7561
Andre Williams v. *SEPTA, et al.*	No. 87-1258
Matthew Cunningham, et al. v. *SEPTA, et al.*	No. 87-5269

ORDER

AND NOW, this 21st day of October, 1992, upon consideration of Defendants' Motion *In Limine* to Exclude the Testimony of Ian C.T. Nisbet, Ph.D., all responses thereto, and a hearing on said motion, it is hereby ORDERED that said Motion is GRANTED.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.

APPENDIX III-C

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master Docket No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

Cathlene Brown, et al. v. *SEPTA, et al.*	No. 86-7415
Celeste Brown, et al. v. *SEPTA, et al.*	No. 86-7416
Christopher S. Brown, et al. v. *SEPTA, et al.*	No. 86-7414
Clemmon Brown, et al. v. *SEPTA, et al.*	No. 86-7420
Cloyd Brown, et al. v. *SEPTA, et al.*	No. 86-7421
Craig Brown, et al. v. *SEPTA, et al.*	No. 86-7419
Curtis Brown, et al. v. *SEPTA, et al.*	No. 86-7422
Mary Retta Johnson, v. *SEPTA, et al.*	No. 86-7418
Margherita Barbetta, v. *SEPTA, et al.*	No. 86-7417

MEMORANDUM

R.F. KELLY, J. October 21, 1992

MOTION IN LIMINE TO EXCLUDE THE
TESTIMONY OF
G. JOHN DiGREGORIO, M.D., Ph.D.

Before the Court is Defendants' Motion to Exclude the Testimony of G. John DiGregorio, M.D., Ph.D. ("Dr. DiGregorio").[1] Dr. DiGregorio is to testify in this toxic

[1] Defendants in this matter are Monsanto Corporation, General Electric Company, Amtrak, Conrail, Southeastern Pennsylvania Transit Authority (SEPTA) and the City of Philadelphia.

tort case on behalf of nine individuals who claim to have been exposed to polychlorinated biphenyls ("PCBs") from the Paoli Railyard ("Railyard"), which is adjacent to their homes in Paoli, Pennsylvania.[2] Dr. DiGregorio is presented as an expert witness to testify that: 1) the Plaintiffs' present injuries were caused by PCB exposure; 2) the Plaintiffs are at an increased risk of developing future injuries due to their exposure to PCBs;[3] 3) the Plaintiffs have an increased fear of future injury and this fear is reasonable; and 4) a medical monitoring program, which he would design, should be implemented for the Plaintiffs.

Defendants seek to exclude this testimony on the grounds that it is based upon unreliable methodology and incomplete data. Furthermore, Defendants contend that his opinions concern subject matters which are outside of his field of expertise, and that his medical monitoring opinion was disclosed in an untimely fashion.

I. PROCEDURAL HISTORY

This case is before the Court on remand. In 1986, Plaintiffs filed their complaints alleging that they suffered various injuries from exposure to PCBs. This Court granted Defendants' Joint Motion for Summary Judgment in 1988. On appeal, the Third Circuit reversed that ruling and remanded this matter for further hearings.

The trial in this matter was scheduled to begin on August 3, 1992. Based on the numerous motions *in limine* filed by the parties, the Court heard six days of

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[2] Those plaintiffs are Cathlene Brown, Celeste Brown, Curtis Brown, Christopher Brown, Cloyd Brown, Craig Brown, Mary Retta Johnson and Margherita Barbetta. For the sake of clarification, Plaintiffs are grouped according to their counsel. The nine Plaintiffs in this action are collectively know as the "Hanes Plaintiffs", named after their counsel, Bruce Hanes.

[3] During oral argument, Plaintiffs' counsel withdrew the claim for increased risk of future injury due to PCB exposure. July 28, 1992 Hearing at 166-68.

testimony and argument concerning these motions. The Court shall now render its findings concerning the testimony of Dr. DiGregorio.

II. FINDINGS OF FACT

1. On June 4, 1991, this Court issued a Scheduling Order by which this case was to proceed. (Attached as Exhibit 1 to the Appendix to Defendants' Motion *in limine*.) This Order required Plaintiffs to supply Defendants with a list of all trial expert witnesses and the substance of their respective testimony by March 17, 1992. Defendants were to provide the same information to Plaintiffs by April 17, 1992. This Order established June 17, 1992 as the deadline for the deposition of all expert witnesses, and August 3, 1992 as the trial date.

2. Prior to the trial date, the parties filed numerous motions *in limine*. This Court heard six days of arguments and live testimony in support of both parties respective motions *in limine*.[4] The record for this particular motion consists of the testimony of Jordan N. Fink, M.D. ("Dr. Fink") July 28, 1992 Hearing Testimony of Dr. Fink ("Fink T.") and Paul M. Roediger, M.D. ("Dr. Roediger") July 28, 1992 Hearing Testimony of Dr. Roediger ("Roediger T."); the videotape deposition of Michael Weitekamp, M.D. ("Dr. Weitekamp") July 28, 1992 Hearing Testimony of Dr. Weitekamp ("Weitekamp Dep."); the transcripts of Dr. DiGregorio's five depositions (Attached as Exhibits 6-10 to the Appendix to Defendants' Motion *in limine*); Dr. DiGregorio's Curriculum Vitae (Attached as Exhibit 4 to the Appendix to Defendants' Motion *in limine*) ("DiGregorio CV"); his reports dated June 13, 1986 and April 21, 1986 (Attached to Exhibit 2 to the Appendix to Defendants' Motion *in limine*); and his Medical Surveillance Program dated

[4] The *in limine* hearings were held on July 28, 29, 30, 31 and August 3, 1992. On August 7, 1992, the Court heard oral arguments on the various motions *in limine* as well as the motion for summary judgment.

April 18, 1992 (Attached as Exhibit 3 to the Appendix to Defendants' Motion *in limine*) ("Surveillance Program").

3. Dr. DiGregorio received his bachelors degree from Pennsylvania State University in 1962. He received his Ph.D. in pharmacology from Hahnemann Medical College ("Hahnemann") in 1966, and his M.D. from Hahnemann in 1978. From 1978 to 1979 he served an internship in internal medicine at Hahnemann Hospital. Dr. DiGregorio completed his residency at Hahnemann in 1981, and became board eligible in internal medicine in that same year. He is licensed to practice in the Commonwealth of Pennsylvania and has been a professor of pharmacology and medicine at Hahnemann from 1981 to the present. During his career he has written in excess of thirty research articles and authored over twenty books. DiGregorio CV.

4. Dr. DiGregorio was deposed in this matter on April 4, April 26, June 2 and June 3, 1988. (Attached as Exhibits 6-9 to the Appendix to Defendants' Motion *in limine*) ("DiGregorio 1988 Dep.") The only other occasion in which he was deposed for this case was April 16, 1992. (Attached as Exhibit 10 to the Appendix to Defendants' Motion *in limine*) ("DiGregorio 1992 Dep.")

5. Dr. DiGregorio is presented as an expert witness on behalf of the Hanes Plaintiffs. He offers the opinions that the Plaintiffs' present injuries were caused by PCB exposure, that Plaintiffs have an increased fear of future injuries and such fear is reasonable, and that a medical monitoring program should be implemented for the Plaintiffs.

6. Dr. DiGregorio met with each plaintiff on one occasion in 1986.[5] He intended these initial visits to be

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[5] Dr. DiGregorio did meet again with Christopher Brown in March of 1988 to treat him for a rash. DiGregorio 1988 Dep. 430. He also saw Mary Retta Johnson on one other occasion in order to perform more blood work. *Id.* at 423.

merely "fact finding" meetings so he could obtain their histories and "get my facts in order". DiGregorio 1988 Dep. 204.

7. Dr. DiGregorio's evaluation of each plaintiff consisted of the following:

a) Each Plaintiff filled out a Medical Surveillance Check List ("check list"). This check list required Plaintiffs to mark the symptoms they had and answer various questions concerning their family medical history.

b) Upon completing the check list, each Plaintiff was interviewed by Dr. DiGregorio in order to discuss the responses on the check list.

c) Each Plaintiff had blood drawn in Dr. DiGregorio's office. This blood was tested and measured for PCB content.

d) Each Plaintiff had a fat biopsy performed at a local hospital. These biopsies were tested and measured for PCB content.[6] *Id.* at 193-94, 390.

8. Dr. DiGregorio did not perform a physical examination, did not perform a psychological examination, nor did he review medical records for any of the Plaintiffs. *Id.* at 341, 349, 397, 398, 429, 454-55, 475.

9. Based on this procedure, Dr. DiGregorio opined that the Plaintiffs had the following symptoms:

a) Craig Brown had a limited range of motion in his arms, legs, head and neck. He complained of headaches, a tumor on his breast, a heart murmur and arthritic pain. His blood test revealed that his LDH was elevated. *Id.* at 263-65, 268-69.

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[6] Cloyd Brown was not evaulated by Dr. DiGregorio for PCB exposure except to have a fat biopsy performed. Mr. Brown did not fill out a check list, was not interviewed by Dr. DiGregorio nor did he have any blood drawn. He was seen by Dr. DiGregorio in September of 1986 for a cyst on his thigh. DiGregorio 1988 Dep. 472-75.

b) Christopher Brown had hypertension and a heart murmur. His blood test revealed that he had a liver dysfunction and elevated triglyceride. *Id.* at 108-11, 439-40, 442-44.

c) Curtis Brown was irritable, had insomnia and a heart murmur. His blood test revealed that he had an abnormal liver function and elevated trigylceride. *Id.* at 347, 355, 359, 366.

d) Cathlene Brown bruised easily, had stiff joints, tender joints and swelling of the hands and feet. *Id.* at 374-75.

e) Mary Retta Johnson was irritable and suffered from insomnia, anxiety, depression and a sluggish thyroid. Her blood test revealed that she suffered from anemia. *Id.* at 396, 398, 417.

f) Celeste Brown had a thyroid problem and a heart murmur. *Id.* at 459-60, 464.

g) Margherita Barbetta checked that she developed diabetes in 1984. *Id.* at 458.

h) Clemmon Brown suffered from dizziness and high blood pressure. *Id.* at 467-68.

10. In addition to the above delineated symptoms, Dr. DiGregorio opined that each Plaintiff suffered from anxiety and an increased fear of developing future illnesses, most notably cancer. *Id.* at 323, 357, 384, 425.

11. In 1988, Dr. DiGregorio's diagnosis was that all of the Plaintiffs' symptoms were caused by exposure to PCBs "until proven otherwise." *Id.* at 377-78. Inconsistent with this diagnosis, Dr. DiGregorio admits that until he physically examines the Plaintiffs he is unable to know if they presently suffer from *any* injuries. *Id.* at 340, 41, 369-70, 384, 390, 400-01, 449-50, 465, 469. Furthermore, Dr. DiGregorio is unable to state an opinion as to whether any of the Plaintiffs will develop future injuries

due to PCB exposure. *Id.* at 343, 372, 390. The only opinion that Dr. DiGregorio is consistent in holding throughout his deposition is that the Plaintiffs' anxiety, fear of cancer, depression and abnormal lab values were caused by exposure to PCBs. *Id.* at 475-76.

12. In rendering his opinion that PCBs were the cause of all of the Plaintiffs' symptoms, Dr. DiGregorio failed to consider and further test for alternative causes of these symptoms. Most notably:

a) Dr. DiGregorio concluded that Craig Brown's elevated LDH, which is a liver enzyme, was caused by PCB exposure. In addition, he testified that alcohol is also a cause of elevated LDH. Dr. DiGregorio was unaware that Craig Brown admitted to his psychologist that he drank a few cans of beer every work night, and 2 to 3 six packs on Thursday, Friday and Saturday nights. *Id.* at 313-15. However, Dr. DiGregorio testified that this knowledge of Craig's drinking habits would not affect his opinion that PCB exposure was the cause of Craig Brown's elevated LDH. *Id.* at 313-15.

b) Cathlene Brown checked that she bruised easily. *Id.* at 374. Without performing a physical examination to verify that she did in fact have bruises, Dr. DiGregorio concluded that her bruising was caused by PCB exposure. *Id.* at 375-76. Even though Cathlene Brown was taking the birth control pill Ortho-Novum and that a side effect of this is bruising, Dr. DiGregorio maintained that PCB exposure was the cause of her bruising. *Id.* He stated that he would continue to hold this opinion until he had the opportunity to further investigate the matter "either by physical examination or more tests. . . ." *Id.* at 377.

c) Curtis Brown checked that he was irritable and had insomnia. *Id.* at 347. Dr. DiGregorio stated that there are many causes of insomnia and irritability and that they are non-specific symptoms. *Id.* at 350. How-

ever, without reviewing Curtis Brown's medical records or performing a physical examination of him, Dr. DiGregorio concluded "to a reasonable degree of medical certainty" that PCB exposure was the cause of his insomnia and irritability. *Id.* at 349-51. Dr. DiGregorio conceded that this was merely his preliminary opinion and that this opinion may change upon future physical examinations and tests. *Id.* at 349-50.

d) Dr. DiGregorio testified that Curtis Brown's elevated triglycerides, as revealed by his blood tests, was caused by PCB exposure. *Id.* at 366. When questioned about the type of blood sample he used, Dr. DiGregorio stated that he used a non-fasting blood sample. He admitted that the use of a non-fasting blood sample tended to incorrectly show elevated triglycerides. *Id.* at 364-65. In fact, he stated that to get a "true value of triglycerides", one should use a fasting blood sample rather than a non-fasting sample. *Id.* at 364-66. He also stated that obtaining a fasting blood sample would be the first thing that he would do to determine the cause of Curtis Brown's elevated triglycerides. *Id.* at 366. In addition, Dr. DiGregorio stated that diet and hypertension can cause elevated triglycerides, but he did not inquire into Curtis Brown's diet or stress level. *Id.* at 366-68. Even though Dr. DiGregorio used a less reliable non-fasting blood sample and did not consider Curtis Brown's diet or stress level, Dr. DiGregorio opined "with a reasonable degree of medical certainty, his elevated triglycerides are due do [sic] to PCB [exposure]." *Id.* at 365-67.

13. During his deposition in 1988, Dr. DiGregorio described his methodology which led him to diagnose PCB exposure as the cause of all of the Plaintiffs' symptoms.

> A. When a doctor does a history and there's a cause of a problem, whether it's pneumonia, pulmonary tract infection, and the differential diagnosis—the leading differential diagnosis at

the time is what the doctor suspects is the immediate cause of the problem.

And it's up to the doctor to proceed after that point and to prove either by physical examination or more tests whether his diagnosis is correct.

So, as far as I'm are [sic] concerned the symptoms that these patients gave me in the history are due to PCB exposure. Until I have the opportunity to continue on with my investigation they all will have, within a reasonable degree of medical certainty, that type of symptom.

Q. I don't mean to put words in your mouth, but isn't that really the preliminarily [sic] assessment or preliminary diagnosis?

A. That's what I've been telling you all along now. I only preliminarily saw these individuals. It's a diagnosis at this time.

Id. at 377-78.

14. Dr. DiGregorio concedes that, based on the limited information he had, he is unable to make a final diagnosis. In addition, he must prove his preliminary diagnosis before he can render a final opinion. *Id.* at 379.

15. As Dr. DiGregorio attested to, since he did not perform a physical examination of these Plaintiffs, he cannot verify the *existence* of their claimed injuries. *Id.* at 268-69, 356, 398, 449-50, 475. Furthermore, Dr. DiGregorio did not inquire into whether the Plaintiffs had seen a doctor for these claimed injuries. I find that Dr. DiGregorio merely assumed that the Plaintiffs suffered from these problems, and he failed to verify this through any medical examination or procedure.

16. Dr. DiGregorio testified that "[t]he plan was to continue on as a follow-up [basis] and to do physical

examinations . . . ." *Id.* at 354. These follow-up visits were necessary in order to prove whether or not his initial diagnosis was correct. *Id.* at 377. These follow-up visits would consist of obtaining a complete medical history of each Plaintiff, performing physical examinations and more blood tests as the physical examinations showed necessary, performing a chronological exposure history, and studying the type of exposure that the Plaintiffs were subject to as well as its source. *Id.* at 304-05, 354, 385-86, 510-12. When asked in 1988 how long it would take to complete these follow-up visits, Dr. DiGregorio believed that everything could be concluded within six months. *Id.* at 510-12.

17. Dr. DiGregorio also testified that all of the Plaintiffs had an increased fear of developing future illnesses, most notably cancer. *Id.* at 99-100. He stated that he "can determine as a physician whether the person is under a great deal of stress, or a lot of anxiety, or a lot of fear." *Id.* at 208. However, Dr. DiGregorio admitted that he could not quantitate that increased fear because he is not an expert at measuring fear. *Id.* at 207. Dr. DiGregorio admitted that his determination that the Plaintiffs had a high degree of anxiety and an increased fear of developing cancer was purely subjective. *Id.* at 341. Furthermore, he did not perform a psychological examination of any of the Plaintiffs. *Id.* at 321, 349, 398, 429, 439, 454-55. According to Dr. DiGregorio, there are tests that can be performed to quantitate fear, but he is not able to perform those tests, and to his knowledge, none of these tests have been performed on the Plaintiffs. *Id.* at 211-12.

18. Dr. DiGregorio further opined that the Paoli Railyard was the source of the PCBs to which the Plaintiffs were exposed. *Id.* at 303-04. He did not have any data as to the levels of PCBs in the Railyard or in the Plaintiffs' living areas when he made this statement. *Id.* He was told by various Plaintiffs that they had been ex-

posed to PCBs, to PCB dust and vapors, and that they could smell the PCBs. *Id.* at 254-55, 267-68, 352, 430-31. Dr. DiGregorio merely relied on these statements in concluding that the PCBs came from the Paoli Railyard.

19. In the four years since stating that follow-up visits were necessary in order for him to make a final diagnosis, Dr. DiGregorio has yet to see any of the Plaintiffs for these follow-up visits, nor has he "done anything with them." DiGregorio 1992 Dep. 55. In addition, he testified that he has not performed any more research "with respect to the relationship between [the] level of exposure of PCBs, and [the] cause of illness or any kind of illness." *Id.* Dr. DiGregorio has not performed physical examinations of the Plaintiffs, has not reviewed their medical records and has not had any additional lab work done. *Id.* at 14, 32-33, 55.

20. In his 1992 deposition, Dr. DiGregorio stated that the Plaintiffs should be the subjects of a medical monitoring program. *Id.* at 28. According to Dr. DiGregorio, this is necessary because Plaintiffs are at an increased risk of contracting various illnesses due to their exposure to PCBs. *Id.* at 25-26, 35-36. Since PCBs affect several organs in the body, this comprehensive monitoring program would provide a method for the early detection of any illness. *Id.* at 36, 65-66. As of his 1992 deposition, Dr. DiGregorio had not been requested to develop a monitoring program for the Plaintiffs. *Id.* at 29. In fact, when questioned by Defendants' counsel on this matter, Dr. DiGregorio refused to answer any questions regarding a medical monitoring program because one had yet to be developed. However, on April 18, 1992, *two days* after this deposition, Dr. DiGregorio submitted to Plaintiffs' counsel his Medical Surveillance Program in which he outlined the monitoring that the Plaintiffs should undergo for at least the next twenty-five years.

21. As was the case in 1988, Dr. DiGregorio cannot quantify Plaintiffs' increased risk of getting cancer or any other illness due to PCB exposure. *Id.* at 57-58. In fact,

Dr. DiGregorio merely assumes that all of the Plaintiffs are extremely sensitive to PCBs, such that even the slightest exposure will cause serious injuries. *Id.* at 76.

22. At the *in limine* hearing, Defendants presented the live testimony of Dr. Fink, Dr. Roediger and the video tape deposition of Dr. Weitekamp. These witnesses outlined the proper methodology that physicians must follow in rendering a medical diagnosis. These expert witnesses were presented specifically to rebut the testimony of Janet D. Sherman, M.D. ("Dr. Sherman"), but I find their testimony equally applicable to the methodology of Dr. DiGregorio.

23. Defendants offered Dr. Fink as an expert in internal medicine and immunology. Dr. Fink graduated with a bachelors degree from the University of Wisconsin in 1956. He obtained his M.D. from the University of Wisconsin Medical School in 1959. After two years of rotating internships, Dr. Fink performed a three year residency in internal medicine at Milwaukee County General Hospital. During his career, Dr. Fink has written in excess of 230 articles and has performed research concerning unusual lung diseases and the immune responses of the lungs. Dr. Fink is currently a Professor of Medicine as well as Chief of the Allergy and Immunology Division at the Medical College of Wisconsin. He teaches immunology and serves on various committees which oversee the quality of the clinical care rendered by the physicians at the Medical College. He is board certified in allergy and immunology as well as internal medicine. His current practice consists of seeing sixteen new patients and one hundred return patients per week. In addition, he makes internal medicine ward rounds six weeks out of the year. Fink T. 11-16.

24. At the *in limine* hearings, Dr. Roediger was offered as an expert in internal medicine. Dr. Roediger graduated with a bachelors degree from Princeton University in 1954. After obtaining his M.D. from Thomas

Jefferson University Hospital in Philadelphia in 1958, Dr. Roediger served a one year internship and a three year residency in internal medicine at Abington Memorial Hospital. Since 1963, Dr. Roediger has been the Director of Medical Education for the hospital, which currently has eighty residents in training. In this capacity, Dr. Roediger has managed the internal medicine program and been the administrator for all four primary care programs as well as staff qualifications and licensure. In 1972, he was appointed Physician and Chief of General Internal Medicine, a position which he holds to this day. Dr. Roediger is also responsible for the quality of care offered by the internists at the hospital. He is board certified and his current practice consists of seeing approximately 125 patients per week. Roediger T. 93-97.

25. By means of videotape deposition, Defendants offered Dr. Weitekamp as an expert in internal medicine and immunology. Dr. Weitekamp received his M.D. from Georgetown University in 1977. He then went to Hershey Medical Center where he was trained in internal medicine and infectious diseases. From 1985 to 1990, Dr. Weitekamp was Chairman of the Department of Medicine at Polyclinic Medical in Harrisburg. At Polyclinic, Dr. Weitekamp served on the Medical Resident Clinical Competency Committee, Medical Education Committee and the Quality Assurance Committee. Dr. Weitekamp is currently Chief of the Division of Internal Medicine at Hershey. He is also an associate professor in internal medicine and infectious diseases at Penn State University, where he teaches medical students and residents. Dr. Weitekamp has published eleven peer review articles and authored chapters in four text books. He is licensed to practice in Pennsylvania, and he currently has an office practice in internal medicine and infectious diseases. In addition, he serves as an attending physician in a teaching setting for four months out of the year. Weitekamp Dep. 6-10.

26. During the *in limine* hearings, Drs. Fink, Roediger and Weitekamp testified as to the proper process that a physician should follow when diagnosing a patient's illness. That process is as follows:

a) It begins by asking the patient what is his/her chief complaint.

b) Then a history is taken which "delves into the chief complaint and expands the nature, the timing, the associated complaints that the patient might have." Fink T. 18-19.

c) Then the symptoms are reviewed to determine which organs are involved in the illness.

d) A past medical history is taken.

e) A social history is taken, which would pertain to the patient's drug, smoking, drinking and sexual habits.

f) A physical examination would then be performed with an emphasis placed on the chief complaint.

g) After all of the above is completed, a differential diagnosis is performed in order to determine the cause of the patient's complaint. A differential diagnosis consists of listing the possible diagnoses, examining each and "ruling in" those that appear to be the likely cause and "ruling out" those that do not appear to be the cause. Additional tests may be run which will support or eliminate some of the diagnoses.

h) If several diagnoses remain, then a more extensive evaluation of the patient is required. This necessitates running more tests, asking more questions and examining medical records until the problem is resolved. Fink T. 17-19, Roediger T. 117-22, Weitekamp Dep. 60-62.

27. These expert witnesses testified that performing a differential diagnosis is the fundamental duty or the "hallmark" of internal medicine. Fink T. 43, Roediger T. 117, Weitekamp Dep. 62. Without considering alternative causes, and then ruling them in or out as a cause of the

patient's complaint, a physician's diagnosis is "totally unreliable." Fink T. 43.

28. This Court finds that reliable medical methodology requires a physician to perform a differential diagnosis and thus, evaluate alternative causes before rendering an opinion as to the cause of an illness.

29. In fact, this is precisely what Dr. DiGregorio intended to do in his follow-up visits with the Plaintiffs. He intended to perform physical examinations, take medical histories, perform more tests and study the source and amount of Plaintiffs' exposure. DiGregorio 1988 Dep. 304-05, 354, 385-86, 510-12. This needed to be performed so that he may render a correct, final diagnosis. However, Dr. DiGregorio testified that this has not been done in the six years since he has first seen the Plaintiffs. DiGregorio 1992 Dep. 55.

III. CONCLUSIONS OF LAW

1. This Court held *in limine* hearings as advised by *United States v. Downing*, 753 F.2d 1224 (3d Cir. 1985) to examine the admissibility of the testimony of the Hanes Plaintiffs' expert witness, G. John DiGregorio, M.D., Ph.D. Findings of Fact ("FF") ¶ 2. In addition to the motions and exhibits filed, the Court heard live testimony and oral arguments concerning the admissibility of Dr. DiGregorio's testimony. FF ¶ 2.

A. *Present Injuries and Causation*

2. Defendants seek to exclude Dr. DiGregorio's testimony regarding the injuries that the Plaintiffs currently have and their respective causes. Defendants claim that his opinions are based on unaccepted methodology and inadequate data, and are therefore inadmissible under Federal Rules of Evidence 702 and 703. ("Rule 702") ("Rule 703").

1. *Rule 702*

3. Defendants contend that Dr. DiGregorio's methodology is unreliable, and as such should be excluded pursuant to Rule 702.[7] "When it is a scientist's methodology that is being attacked, in contrast to the data relied on, the court must analyze the reliability of that methodology under . . . Rule 702." *In re Paoli R.R. Yard PCB Litigation,* 916 F.2d 829, 856-57 (3d Cir. 1990), *cert. denied sub nom. General Elec. Co. v. Knight,* 111 S. Ct. 1524 (1991). Defendants attack Dr. DiGregorio's methodology which consisted of seeking each Plaintiff on one occasion, having each Plaintiff fill out a check list of symptoms, interviewing each Plaintiff concerning this check list, and performing a blood test and a fat biopsy. FF ¶ 7.

4. Plaintiffs argue that the Defendants' failure to put forth any testimony which directly contradicted Dr. DiGregorio's methodology compels the admission of him as an expert witness. Plaintiffs are incorrect in their asessment. Drs. Fink, Roediger and Weitekamp all testified as to the proper methodology that should be followed in diagnosing an illness. FF ¶¶ 2, 22-28. Even though their testimony was used to directly contradict the testimony of Dr. Sherman, it has been found to be equally applicable to Dr. DiGregorio. FF ¶¶ 22, 28. Furthermore, Defendants are not required to produce testimony which directly contradicts the opinions of Dr. DiGregorio. The only requirement is that "there be a developed record and specific findings on reliability issues." *Paoli,* 916 F.2d at 858. This Court has complied with that requirement. FF ¶ 2.

5. The testimony of Defendants' experts demonstrates that the methodology used by Dr. DiGregorio is neither

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[7] Rule 702 states: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise."

standard nor reliable. FF ¶¶ 22-28. Defendants' expert witnesses testified that a physician must perform a physical examination, medical and social histories as well as differential diagnosis before rendering a final opinion. FF ¶¶ 26-28.

6. Furthermore, and of greater significance, Dr. DiGregorio did not follow the methodology that *he* proposed would be necessary to render a proper final diagnosis. FF ¶¶ 14, 16, 29. The methodology that he intended to follow would consist of a complete medical history of each Plaintiff, a physical examination, performing more blood tests as well as other tests that the physical examination showed necessary, performing a chronological exposure history and studying the type of exposure that the Plaintiffs were subject to as well as its source. FF ¶ 16. It is undisputed that Dr. DiGregorio did not follow this methodology. FF ¶¶ 29. As a result, Dr. DiGregorio is only able to render a preliminary diagnosis. FF ¶¶ 13-15, 29.

7. Rule 702 calls for the admission of an expert's testimony "so long as it is rendered by a qualified expert and is helpful to the trier of fact". *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 954 (3d Cir. 1990). This helpfulness requirement is the "touchstone of Rule 702." *United States v. Downing*, 753 F.2d 1224, 1235 (3d Cir. 1985). The Court is cautioned that, "in making reliability determinations, courts must err on the side of admission rather than exclusion." *Paoli*, 916 F.2d at 857. However, "expert testimony that is based on unreliable methodology is unhelpful and therefore excludable." *DeLuca*, 911 F.2d at 954.

8. In his 1988 deposition, Dr. DiGregorio stated that he intended to perform various tests in his follow-up visits with each Plaintiff in order to prove or disprove his preliminary diagnosis. FF ¶ 16. However, as of four years later, Dr. DiGregorio has yet to see any Plaintiff on a follow-up visit nor has he "done anything with

them." FF ¶¶ 19, 29. He has not proved or disproved his preliminary diagnosis to the Plaintiffs, the Court, or more importantly, himself.

9. Dr. DiGregorio's intentions were proper methodology, but his actions, or lack thereof, were not. It is this incompleteness which "so altered [the methodology] as to skew the methodology itself" and renders it unreliable. *Paoli*, 916 F.2d at 858. Without the *performance* of proper methodology, Dr. DiGregorio's opinions are only preliminary, and as such are unhelpful to the jury. Since this incomplete methodology is unhelpful to the jury, his opinion on this matter is excluded pursuant to Rule 702.

10. In further support of their Rule 702 argument, Defendants contend that Dr. DiGregorio's testimony should be excluded because he failed to consider alternative causes of Plaintiffs' alleged injuries as required by proper methodology. FF ¶¶ 12, 26-28. Drs. Fink, Roediger and Weitekamp testified that proper methodology demands that the physician perform a differential diagnosis, which is ruling in or ruling out alternative causes of the patient's injury. FF ¶¶ 26-28. Plaintiffs correctly maintain that Dr. DiGregorio need not rule out all other possible causes of the symptoms in order to be admitted as an expert. However, he is not asked to rule out all other possible causes of Plaintiffs' injuries. He is merely expected to use proper methodology in rendering an opinion concerning a patient's injuries. This proper methodology requires that he evaluate alternative causes so that he may render the correct diagnosis. FF ¶¶ 26-28. After all, the purpose of an expert witness is to assist the trier of fact in rendering an intelligent, sound and correct verdict. *Viterbo v. Dow Chemical*, 826 F.2d 420, 422 (5th Cir. 1987). This is achieved by the expert isolating the cause of the injuries and providing supporting medical reasons for the diagnosis. Dr. DiGregorio's failure to evaluate alternative causes of Plaintiffs' alleged injuries forces the jury to arbitrarily choose one cause from a plethora of possible causes, and no medical foundation to aid them in

making that choice. FF ¶ 12. Therefore, I conclude that Dr. DiGregorio's unsupported opinion does not give the finder of fact a better understanding of the cause of Plaintiffs' alleged injuries.

11. Plaintiffs are also correct in their statement that to meet the standard for admissibility in this Circuit, it need only be shown that PCBs were a substantial contributing factor in Plaintiffs' injuries, not the only factor. *Van Buskirk v. Carey Canadian Mines, Ltd.*, 760 F.2d 481, 492 (3d Cir. 1985). However, Dr. DiGregorio admits that until he performs a physical examination, he is unable to verify the *existence* of the Plaintiffs' claimed injuries. FF ¶¶ 11, 13-15. For instance, Craig Brown and Christopher Brown each stated they had heart murmurs, but in both cases Dr. DiGregorio did not listen to their hearts, which he testified was necessary to do in order to determine the existence of a heart murmur. FF ¶¶ 9, 11, 15. Craig Brown stated that he had a tumor on his breast, but Dr. DiGregorio did not examine Craig for this alleged tumor. FF ¶¶ 9, 11, 15. Clemmon Brown stated that he had high blood pressure, yet Dr. DiGregorio did not take Clemmon's blood pressure, nor did he inquire into whether Clemmon was on any medication for that problem. FF ¶¶ 9, 11, 15. This Court is unable to fathom how it is possible for Dr. DiGregorio to testify that PCBs were a "substantial contributing factor" to Plaintiffs' injuries when he does not know if the Plaintiffs have any injuries. *Van Buskirk*, 760 F.2d at 492.

12. Because Dr. DiGregorio failed to have follow up visits with the Plaintiffs, failed to consider alternative causes of Plaintiffs' alleged injuries and failed to verify the existence of Plaintiffs' complaints, this Court concludes that his methodology is incomplete and therefore unreliable. As such, the testimony of Dr. DiGregorio is unhelpful to the finder of fact and excluded pursuant to Rule 702.

2. *Rule 703*

13. Defendants also assert that Dr. DiGregorio's testimony should be excluded pursuant to Rule 703 because it relies on data that experts in the field do not find reliable.[8] Rule 703 is used to determine if "an expert's testimony is based on the type of data a reasonable expert in the field would use in rendering an opinion on the subject at issue. . . ." *Paoli*, 916 F.2d at 857. In analyzing a Rule 703 motion, this Court adheres to the principle that "the proper inquiry is not what the court deems reliable, but what experts in the field find reliable." *In re Japanese Elec. Prod.*, 723 F.2d 238, 277 (3d Cir. 1983), *rev'd on other grounds sub nom. Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986). The Court has held *in limine* hearings to "make a factual inquiry and finding as to what data experts in the field find reliable." *Id.*; FF ¶ 2.

14. Due to his incomplete and therefore unreliable methodology, the data that Dr. DiGregorio relies upon is likewise unreliable. In forming his opinion that the cause of Plaintiffs' symptoms resulted from exposure to PCBs, Dr. DiGregorio considered the check list that Plaintiffs filled out, a brief interview he held with each Plaintiff and the results from the fat and blood tests. FF ¶¶ 7, 13, 14. As shown by Defendants' expert witnesses, this data alone is inadequate and unreliable to form a medical opinion. FF ¶¶ 26-28. There exists an abundance of other information that reasonable medical personnel should explore before rendering a diagnosis, including performing a complete physical examination; performing medical and social histories; reviewing medical

[8] Rule 703 states:

> The facts of data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

records; and performing a differential diagnosis. FF ¶¶ 26-28. Dr. DiGregorio did not have any of the important information that is ascertained from these medical procedures when he rendered his diagnosis. FF ¶¶ 13, 14, 16. Furthermore, Dr. DiGregorio admits that he needs to explore this other information before rendering a final opinion to "a reasonable degree of medical certainty." FF ¶¶ 11, 13-14.

15. Because experts in the field do not rely upon incomplete information in rendering a diagnosis, Dr. DiGregorio's testimony pertaining to causation is excluded pursuant to Rule 703.

B. *Fear of Future Illnesses*

16. Dr. DiGregorio is also offered as an expert to testify that Plaintiffs have an increased fear of developing future illnesses, that this increased fear stems from their exposure to PCBs and that this fear is reasonable. Defendants challenge his opinion on the grounds that Dr. DiGregorio is not qualified to render this opinion and that his methodology is unreliable. As such, Defendants contend that his opinion should be excluded pursuant to Rule 702.

17. "Rule 702 authorizes the admission of expert testimony so long as it is rendered by a qualified expert and is helpful to the trier of fact." *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 954 (3d Cir. 1990). In interpreting Rule 702, this Court recognizes the established "liberal policy of permitting expert testimony which will 'probably aid' the trier of fact." *Aloe Coal Co. v. Clark Equipment Co.*, 816 F.2d 110, 114 (3d Cir. 1987) (quoting *Knight v. Otis Elevator Co.*, 596 F.2d 84, 87 (3d Cir. 1979)). However, when that witness seeks to testify to facts and conclusions about which he does not possess expertise, that testimony is deemed not admissible. *Wilkinson v. Rosenthal & Co.*, 712 F. Supp. 474, 478 (E.D. Pa. 1989). At the very

minimum, an expert "must possess skill or knowledge greater than the average layman" concerning the area about which the witness seeks to testify. *Aloe Coal,* 816 F.2d at 114.

18. By his own admission, Dr. DiGregorio is not qualified to measure fear in an individual. FF ¶ 17. He is unable to quantify that fear in any manner other than to say that it is increased. FF ¶¶ 17, 21. He is not a psychiatrist nor is he a psychologist. Dr. DiGregorio is a pharmacologist and as such his professional expertise is not in the area of mental health. FF ¶ 3.

19. Recognizing that the "insistence on a certain kind of degree or background is inconsistent with our jurisprudence in this area", the Court is unaware of anything outside of his profession that would qualify Dr. DiGregorio as an expert in this area. *Paoli,* 916 F.2d at 855. While he states that he is able to recognize fear in individuals, no evidence is proffered to show that this ability is any "greater than [that of] the average layman." *Aloe,* 816 F.2d at 114; FF ¶ 17. Dr. DiGregorio does not possess any specialized skill or knowledge that would assist the jury in determining Plaintiffs increased fear, as required under Rule 702.

20. Therefore, I agree with the court in *Friedman v. F.E. Myers Co.,* 706 F. Supp. 376, 381 (E.D. Pa. 1989), in concluding that Dr. DiGregorio is not qualified to testify as an expert concerning Plaintiffs' claims of increased fear. As a result, his opinion on this matter is excluded pursuant to Rule 702.

21. In further support of their argument to exclude Dr. DiGregorio's testimony, Defendants contend that his methodology is unreliable. In rendering his opinion that Plaintiffs suffer from an increased fear of developing future illnesses, Dr. DiGregorio did not perform any mental examinations, take any mental health histories or administer any tests to measure the Plaintiffs' alleged fear. FF ¶¶ 8, 17, 29. In formulating this opinion, Dr. Di-

Gregorio merely relies on Plaintiffs' statements that they were concerned about getting future illnesses as a result of their exposure to PCBs. FF ¶¶ 10-11, 17-18. There is no *medical* basis for his opinion. Dr. DiGregorio admits this when he testifies that his opinion on this matter is purely subjective. FF ¶ 17. This opinion is merely Plaintiffs' statements being restated by a physician, and as such is not an expert opinion.

22. Futhermore, Dr. DiGregorio admits that he is unable to quantify this increased fear in any manner. FF ¶ 17 [U]nless there is a legally significant foundation for a plaintiff's increased risk of harm, a determination of damages for a plaintiff's fear becomes subjective. There must be some basis upon which a plaintiff's fear can be determined to be *reasonable." Sutcliffe v. G.A.F. Corp.*, 15 Phila. 339, 346 (C.P. Phila. 1987). When attempting to prove increased risk or fear, Pennsylvania law requires the party to establish the background levels, as well as the levels of the plaintiffs, so that the jury will be able to compare the two levels and have some reasonable basis to determine the alleged injuries. "One without the other is of no statistical or probative value since it would require sheer speculation. . . ." *Sutcliffe v. G.A.F. Corp.*, 15 Phila. 339, 345 (C.P. Phila. 1987). Dr. DiGregorio's inability to quantify Plaintiffs' fear or increased risk of harm renders his opinion to be of no probative value.

23. Therefore, Dr. DiGregorio's testimony concerning Plaintiffs' claims of increased fear must also be excluded pursuant to Rule 702 because his "diagnosis" lacks any reliable medical methodology and calls for sheer speculation.

C. *Medical Monitoring*

24. Dr. DiGregorio offers the opinion that Plaintiffs should be the subjects of a medical monitoring program in order to provide for the early detection of diseases.

FF ¶ 20. Defendants assert that this testimony should be excluded under Federal Rules of Civil Procedure 37(b) ("Rule 37(b)") as being untimely. Additionally, Defendants seek to exclude this opinion pursuant to Rule 702 because it is based on unreliable methodology.

1. *Rule 37(b)*

25. By Order dated June 4, 1991, this Court set March 17, 1992 as the deadline for Plaintiffs to file their Rule 26(b)(4) statements.[9] FF ¶ 1. At Dr. DiGregorio's final deposition on April 16, 1992, he testified that he had not developed a medical monitoring program for the Plaintiffs, nor had he been requested to do so. FF ¶ 20. However, two days later, Dr. DiGregorio submitted his Surveillance Program in which he outlined the monitoring that the Plaintiffs should undergo for the next twenty five years. FF ¶ 20.

26. Defendants claim that the late submission of this program, in contravention of the Court's Order, calls for its exclusion. Plaintiffs insist that the Rule 26(b)(4) letter dated March 17, 1992 expressly incorporated all facts and opinions of Dr. DiGregorio's prior testimony.[10] However, at his deposition, which occurred one month *after* the Court's deadline, Dr. DiGregorio still could not testify concerning his Surveillance Program because it had not been developed. FF ¶ 20. Since there is no prior testimony concerning the Surveillance Program, it is obvi-

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[9] The Order stated in relevant part: "2. On or before March 17, 1992, plaintiffs shall designate all trial expert witnesses and provide defendants with the substance of their trial testimony and the basis of their opinions at the time of designation in accordance with Rule 26(b)(4)."

[10] This letter stated in relevant part, "Additionally, G. John DiGregorio, M.D., Ph.D. was deposed in these cases. The defendants are fully aware of his curriculum vitae and his opinions regarding the above plaintiffs. Dr. DiGregorio may be called to testify on behalf of the above plaintiffs as to facts and opinions contained in his deposition testimony."

ous that such testimony could not be incorporated into Plaintiffs' March 17th letter. FF ¶ 20. It is not possible to incorporate prior testimony which has not been given.

27. Defendants further assert that admitting this newly developed evidence would greatly prejudice them. One day *after* submitting their own trial expert list, Defendants received a copy of Dr. DiGregorio's Surveillance Program.[11] FF ¶¶ 1, 20. Defendants contend that they will now have to obtain more experts to rebut Dr. DiGregorio's Surveillance Program. This, in turn, will require Defendants' experts to physically examine Plaintiffs, formulate their respective opinions and be deposed concerning these opinions. In addition, Dr. DiGregorio must be deposed concerning the specifics of his Surveillance Program.

28. There are four factors that a court should consider when deciding to exclude testimony for violation of an order: a) the prejudice or surprise of the party against whom the witness would have testified; b) the ability of that party to cure the prejudice; c) the extent to which allowance of the testimony would disrupt the order and efficiency of the trial; and d) the bad faith or willfulness in failing to comply with the court's order. *Myers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977).

29. Plaintiffs claim that the Defendants would not be surprised by this testimony because Dr. DiGregorio testified about a medical surveillance program on three instances, and the March 17th letter incorporated those statements. As previously stated, there was no incorpora-

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[11] The Courts' Order stated in relevant part: "On or before April 17, 1992, defendants shall designate all trial expert witnesses and provide the plaintiffs with the substance of their trial testimony and the basis for their opinions at the time of designation in accordance with Rule 26(b)(4)."

tion of prior testimony concerning the specifics of his Surveillance Program because it had yet to be developed as of the March 17th letter. Furthermore, on those prior occasions to which Plaintiffs refer, Dr. DiGregorio merely generalized as to medical monitoring programs. FF ¶ 20. At no time did he testify concerning the specifics of his Surveillance Program that would be presented at trial. In fact, Dr. DiGregorio stated that he had not been asked to develop such a program as of his 1992 deposition. FF ¶ 20. Furthermore, Dr. DiGregorio stated that he would have to review medical records of the Plaintiffs before he would be able to develop a program, and he had very few of the Plaintiffs' medical records at the time. FF ¶¶ 8, 20. He also stated that it would take him *two months* to develop such a program in the event that he was requested to do so. DiGregorio 1992 Dep. 35. However, *two days* after this deposition, Dr. DiGregorio submitted his Surveillance Program. FF ¶ 20.

30. Furthermore, Defendants attempted to question Dr. DiGregorio about this program at his final deposition, but Dr. DiGregorio was unable to render any testimony on the matter because the monitoring program had not been developed. FF ¶ 20. The Defendants are prejudiced in this matter because they have already submitted their list of experts as required by the Court's Order, but are being asked to further pursue this matter. Defendants would have to obtain additional experts to rebut Dr. DiGregorio's Surveillance Program, have these experts perform physical examinations of the Plaintiffs, review medical records, study the source of the alleged exposure, have their experts deposed concerning their opinions and further depose Dr. DiGregorio. All of this had to be completed in sixty days because the Court's Order stated that experts could not be deposed after June 17, 1992. FF ¶ 1.

31. Even though the Plaintiffs stated that Dr. DiGregorio would be available to testify on this matter at the Defendants' convenience, the Defendants would not

be able to cure this prejudice. There was merely too much required to properly respond to the Surveillance Program, and too little time in which to do it.

32. Furthemore, the Court's Order was dated June 4, 1991, which gave the Plaintiffs approximately nine and one-half months to develop a monitoring program. FF ¶ 1. This was obviously plenty of time, because it only took Dr. DiGregorio *two days* to develop the program once asked to proceed with it. FF ¶ 20.

33. Moreover, the allowance of this testimony would seriously disrupt the orderly and efficient procedure of this trial. A prolonged continuance would have to be granted to allow for the proper discovery of this matter. When one is allowed in excess of nine months to develop a medical monitoring program, choosing to wait until the last minute to develop such program does not provide reasonable justification for a continuance.

34. Finally, the Court finds that there is bad faith and willfulness on the part of Plaintiffs in failing to comply with the Court's Order. Plaintiffs were given nine and one-half months to develop a monitoring program. FF ¶ 1. The Plaintiffs' attorneys merely had to ask Dr. DiGregorio to proceed with the development of this program, and it is shown that two days later a completed program would be in their hands. FF ¶ 20. The Plaintiffs' attorney could have made this request at any point during the nine and one-half months between the issuance of the Court's Order and the March 17th deadline. Their lack of diligence in this matter constitutes a willful failure to comply with the Court's Order under *Pennypack*.

35. Based on the foregoing, Dr. DiGregorio's Surveillance Program is excluded pursuant to Rule 37(b).

2. *Rule 702*

36. Defendants further contend that Dr. DiGregorio's medical monitoring program should be excluded under Rule 702 because his methodology is unreliable.

37. To make out a claim for medical monitoring, it must be established that:

> 1. Plaintiff was significantly exposed to a proven hazardous substance through the negligent actions of the defendant.
>
> 2. As a proximate result of exposure, plaintiff suffers a significantly increased risk of contracting a serious latent disease.
>
> 3. That increased risk makes periodic diagnostic medical examinations reasonably necessary.
>
> 4. Monitoring and testing procedures exist which make the early detection and treatment of the disease possible and beneficial.

Paoli, 916 F.2d at 852.

38. In ruling upon this issue, the Court recognizes that "the appropriate inquiry is not whether it is reasonably probable that plaintiffs will suffer harm in the future, but rather whether medical monitoring is, to a reasonable degree of medical certainty, necessary in order to diagnose properly the warning signs of disease." *Paoli*, 916 F.2d at 851.

39. In formulating his opinion that medical monitoring was necessary, Dr. DiGregorio relied on Plaintiffs' beliefs that they were exposed to PCBs and that the Paoli Railyard was the source of the PCBs. FF ¶ 18. He did not perform any studies to examine the amount, duration or source of the alleged exposure. FF ¶¶ 16, 19. He admitted that he needed to perform studies concerning the type of exposure that the Plaintiffs were subject to as well as its source before he could render a final opinion. FF ¶¶ 14, 16, 29. As of his April 16, 1992 deposition, Dr. DiGregorio has not performed any of these tests. FF ¶ 29. Dr. DiGregorio's methodology in rendering this opinion is non-existent, and therefore completely unreliable. Mere assumptions and acceptance of a patient's beliefs do not form a reliable medical basis for an expert

opinion. As such, his opinion is unhelpful to the jury and excluded pursuant to Rule 702.

40. Furthermore, Dr. DiGregorio does not meet the standard required in this Circuit to testify as to the need for a medical monitoring program. This Circuit requires that it be shown, "to a *reasonable degree of medical certainty,*" that medical monitoring is "necessary in order to diagnose properly the warning signs of disease." *Paoli*, 916 F.2d at 851 (emphasis added). By merely relying on the statements of the Plaintiffs, failing to verify his preliminary diagnosis and failing to perform any tests concerning the amount and source of PCB exposure, Dr. DiGregorio's opinion is not "to a reasonable degree of medical certainty." *Id.*; FF ¶¶ 13-16, 18-19, 29.

41. As such, it is obvious that Dr. DiGregorio's opinion cannot aid in proving any of the elements needed to make a claim for medical monitoring. Because of his lack of proper methodology, Dr. DiGregorio is unable to show that "plaintiff[s] [were] significantly exposed to a hazardous substance," or that the exposure came from the Railyard, as is required under the first element of a claim for medical monitoring. *Paoli*, F.2d at 852. Furthermore, Dr. DiGregorio is unable to provide a reliable medical diagnosis that Plaintiffs' alleged injuries are a "proximate result of exposure" to PCBs. *Id.* As such, this testimony fails to aid in the proof of the second element of a cause of action in medical monitoring, namely that "[a]s a proximate result of exposure, plaintiff suffers a significantly increased risk of contracting a serious latent disease." *Id.*

42. Because Dr. DiGregorio's methodology was nonexistent, and as such unhelpful to the jury, his testimony concerning his Surveillance Program is excluded.

43. In addition, Defendants assert that the recent Pennsylvania Superior Court decision in *Marinari v. Asbestos Corp., Ltd.*, No. 90-1816, 1992 WL 165252 (Pa. Super. July 20, 1992) draws into question the validity of

a cause of action for medical monitoring in this state. In *Marinari,* the plaintiff-husband was diagnosed in 1983 as having pleural thickening. In 1987, he was diagnosed as having lung cancer. Plaintiffs, husband and wife, filed their complaint in 1987 seeking damages attributable to the cancer, which they claim was caused by asbestos exposure. The statute of limitations for personal injuries in Pennsylvania is two years. 42 Pa.C.S. § 5524(2). The trial court granted defendants' motion for summary judgment on the basis that the plaintiffs' complaint was barred by the statute of limitations. In reversing the trial court, the Superior Court stated that:

> Recovery can be had in a first action only for a disease which has already manifested itself from the exposure to asbestos and the natural, predictable progression, if any, of that disease. If additional injuries from a separate disease manifest themselves in the future, such injuries will support a second action."

Marinari, 1992 WL 165252 at *3. According to Defendants, *Marinari* has made Pennsylvania a two disease state.

44. Since Dr. DiGregorio's testimony has been excluded on other grounds, the Court is not faced with the issue of whether there exists a cause of action for medical monitoring in Pennsylvania in light of *Marinari.* Therefore, the Court does not rely on *Marinari* in excluding the testimony of Dr. DiGregorio.

45. I conclude that Dr. DiGregorio's testimony concerning a medical monitoring program is excluded pursuant to Rule 37(b) and Rule 702 as expressed above.

IV. CONCLUSION

For the foregoing reasons, I find that Dr. DiGregorio's testimony shall be excluded, and I shall accordingly enter the following order:

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master Docket No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS ORDER RELATES TO:

Cathlene Brown, et al. v. *SEPTA, et al.*	No. 86-7415
Celeste Brown, et. al. v. *SEPTA, et al.*	No. 86-7416
Christopher S. Brown, et al. v. *SEPTA, et al.*	No. 86-7414
Clemmon Brown, et al. v. *SEPTA, et al.*	No. 86-7420
Cloyd Brown, et al. v. *SEPTA, et al.*	No. 86-7421
Craig Brown et al. v. *SEPTA, et al.*	No. 86-7419
Curtis Brown, et al. v. *SEPTA, et al.*	No. 86-7422
Mary Retta Johnson, v. *SEPTA, et al.*	No. 86-7418
Margherita Barbetta, v. *SEPTA, et al.*	No. 86-7417

ORDER

AND NOW, this 21st day of October, 1992, upon consideration of Defendant's Motion *In Limine* to Exclude the Testimony of G. John DiGregorio, M.D., Ph.D., all responses thereto, and a hearing on said motion, it is hereby ORDERED that said Motion is GRANTED.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
Judge

APPENDIX III-D

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

George Burrell, et al. v. *Septa, et al.*	No. 86-2235
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
John Narcise, et al. v. *Septa, et al.*	No. 87-1190
Andre Williams v. *Septa, et al.*	No. 87-1258
Charles Stanbach, et al. v. *Septa, et al.*	No. 87-3227
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269

MEMORANDUM

R. F. KELLY, J. October 21, 1992

[As Amended February 1, 1993]

MOTION IN LIMINE TO EXCLUDE EVIDENCE OF ANIMAL STUDIES

This is another in a series of motions *in limine* filed by Defendants Monsanto, General Electric, Westinghouse, Septa, Budd, Amtrak and the City of Philadelphia to exclude evidence of animal studies pursuant to Rules 702 and 703 of the Federal Rules of Evidence. Hearings were held on this and the other motions filed by the parties on July 28, 29, 30, 31 and August 3, 1992. On August 7, 1992, all parties were given the opportunity to argue the motions *in limine* and the motion for summary judgment

now pending before this Court. From the testimony offered on this motion that those hearings, this Court makes the following:

FINDINGS OF FACT

1. Dr. Robert C. James is a toxicologist with a B.S. degree in chemistry and Ph.D. in pharmacology. He has in addition post-doctoral training at Vanderbilt University. James T. 73-75 [1]. Dr. James' post-doctoral work at Vanderbilt involved primarily research dealing with the metabolism or breakdown of chemicals and mechanisms for organ toxicity and primarily liver toxicity related to the metabolism of chemicals. These involved animal studies. After leaving Vanderbilt, Dr. James was the Director of Toxicology for a firm known as Ecology and Environment. That firm was involved in cleaning chemical spills and investigating abandoned waste sites or old spills. As a toxocologist, Dr. James did safety evaluation for field investigation teams and was part of the medical monitoring board that oversaw employees and checked the medical records when there were accidental exposure and evaluated those exposures. James T. 75-76. While he was with Ecology and Environment, Dr. James obtained his first experience in dealing with PCB problems. In 1983, Dr. James moved to the University of Arkansas where he took a position in the Division of Toxicology which was part of the Department of Pharmacology and Toxicology. There he taught graduate students in pharmacology and toxicology and also medical students. However, his primary position there was to conduct research. Currently, he is an Associate Professor at the center for Environmental and Human Toxicology at the University of Florida and is also President of TERRA, Inc. James T. 76-77. At the University of Florida he teaches and conducts research. TERRA, Inc. is a general toxicology consulting firm which conducts research, some of which

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[1] James T. refers to the testimony of Robert C. James given before this Court on July 31, 1992.

is funded by the federal government. It employs approximately 35 people, 10 or 12 of whom have Ph.Ds. Dr. James has authored approximately 50 scientific articles. James T. 78-79. For the last ten years, Dr. James has evaluated and reevaluated the PCB literature and maintains a personal library on this chemical containing over 2,000 scientific articles and 10 to 20 books touching on the various aspects of PCBs. James T. 80.

2. In toxicology, the term exposure is used to mean the eligibility to have contact with a particular chemical. The term dose is used to indicate the amount of chemical that is actually absorbed into the body. James T. 83.

3. The roots of exposure relating to contaminated soil would be incidental soil ingestion, dermal absorption or dermal exposure to soils in the inhalation of dust. The fact that a person may have been exposed to a chemical such as PCBs does not necessary indicate that that person has received a dose of PCBs. James T. 83-84.

4. Dose response relationship is the basic principle that toxicologists use to determine the safety or relative risk of a particular dose that a person has received. It is a mathematical or graphical understanding or the doses over which the chemical produces no effect, and the doses at which it produces whatever adverse effect to which toxicologists are concerned. There is a dose at which all substances will be harmful.

5. In animal studies, each test consists of a toxic endpoint that the researcher is looking at, so you are choosing a toxicity testing method to measure that. James T. 89.

6. There is a legitimate role for animal studies in determining potential human health effects of exposure to chemicals. Since one cannot test chemicals on human beings, it is necessary that you have some organism in which you can identify the possible doses and the possible

adverse effects that might occur in humans if they were to be exposed. James T. 89.

7. Some of the practical problems associated with animal studies are:

(a) Many test animals are bred to be sensitive to a particular type of response; James T. 91.

(b) Rodent tests are extremely sensitive so they identify a large number of chemicals as carcinogens in animals which are likely not to be carcinogens in humans; James T. 92.

(c) Dose is a major factor, "I mean we are pushing the dose of the chemical until we see a toxic effect." When dealing with humans on the other hand there is always an attempt to limit exposure so there will be no toxic effect. James T. 92-93.

(d) Animals have dramatically different physiology, biochemistry and metabolism pathways that break down the toxic chemicals so that, from species to species, there may be differences in bioactivation and detoxification; James T. 92, 93.

(e) Rats and mice are fed ad libitum, they are allowed to eat as much as they want. They become obese and it has been shown that because they are obese it increases the rate of tumors that have been observed; James T. 93.

(f) Test animals are ordinarily dosed with the chemical under study at the "maximally tolerated dose" which is the highest daily dose that the animal can sustain without having a decrease in body weight of more than ten percent. This may result in "metabolic overload" which refers to feeding test animals such high doses that their detoxification mechanism or physiologic processes are so overwhelmed that an abnormal alteration of metabolism is created and affects may be observed at those high doses which would not be observed at lower doses because the same conditions no longer exist in the animal. James T. 94-96.

8. Dr. James testified that approximately 1500 chemicals had been tested in animals and identified to be possible carcinogens in animals, whereas only about 30 chemicals have been identified as carcinogenic in humans. James T. 94. Dr. James further testified that with respect to the other 1,470 chemicals there is no epidemiological evidence that they are carcinogenic in humans, and for a number of them there is clear evidence that they are not carcinogenic in humans. James T. 141-42.

9. It is not valid to extrapolate from tests using high doses in which metabolic overloading occurs to circumstances involving low doses in which metabolic overloading does not occur because as you go down in dose you don't have to go down very far in dose to where you get a situation where the chemical is not causing any of the conditions that you see with the high doses that caused metabolic overloading. James T. 96-97.

10. Dr. James is familiar with the epidemiological studies, as to both morbidity and mortality, which investigate the human health effects of PCBs. In the studies of persons occupationally exposed to PCBs, for example, capacitor workers' dose levels reported are typically 100 to 1000 times higher than people whose body burdens are no different than the rest of the population that has ambient levels or concentrations in blood or fat. James T. 97.

11. The effects seen in maximally tolerated dosed PCB animal studies have not been observed in the studies of highly exposed workers. Therefore, it is not valid to use animal tests results as a basis for an opinion as to the causation of adverse health effects in persons such as the Plaintiffs in this case, who have much lower blood levels. James T. 99. This is true for cancer as well as other human health effects. James T. 99.

12. Animal studies can be validly used to test chemicals that humans have not been yet exposed to in order

to try to understand what possible effects might occur and under what dose. Therefore, before you have humans use a chemical, you would always want to do some basic animal research to identify what toxic effects might occur at various dose concentrations. You would need that in order to develop exposure guidelines so that people could work with those chemicals safely. James T. 101-02. It is Dr. James' opinion and the consensus in the scientific community that the only health effect observed in highly exposed worker populations to PCBs is chloracne. James T. 98, 105-06; *see also* Kimbrough, "Human Health Effects of Polychlorinated Biphenyls [PCBs and Polychlorinated Biphenyls] (PCBs)" American Review of Pharmacology Toxicology, 27 A. Rev. Pharmacal. Toxicol. 87(1987).

13. Dr. James expressed his opinion that it would not be reasonable for a scientist to rely upon animal studies to establish causation in humans in the face of such contradictory epidemiological evidence in studies of humans exposed to PCBs; that it would be an improper and unreliable use of animal data; that it would be improper scientific methodology; and that it would be confusing or misleading. James T. 106-07.

CONCLUSIONS OF LAW

1. Rules 702 and 703 of the Federal Rules of Evidence govern the admissibility of an expert opinion. The Third Circuit has incorporated these rules into a two-prong test for determining whether an opinion is admissible: (1) The opinion must be based upon facts and data of a type "reasonably relied upon by experts in a particular field," Federal Rule of Evidence 703 ("Rule 703"), 703, and (2) The opinion must "assist the trier of fact to understand the evidence or to determine a fact in issue." Federal Rule of Evidence 702 ("Rule 702").

2. In the case of *In re Japanese Electrocinc Products Antitrust Litigation,* 723 F.2d 238 (3d Cir. 1983), *rev'd*

on other grounds sub nom. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574 (1986), the court warned that courts should not admit expert testimony without limitation. Rather, expert testimony should be presented to a jury only after sufficient inquiry into its reliability and foundation. The *Japanese Electronic* court stated that in determining for purposes of Rule 703 whether the informational basis of an expert opinion is of a type reasonably relied upon by experts in the field, "the proper inquiry is not what the court deems reliable, but what experts in the relevant discipline deem it to be." 723 F.2d at 276.

3. In addition to the requirement that the evidence must be of a type reasonably relied upon by experts, Rule 702 requires that the data also be used in a "reliable manner." As stated by the Third Circuit in *United States v. Downing*, 753 F.2d 1224 (3d Cir. 1985), the court must determine that the use of the evidence will assist the trier of fact to determine the evidence or determine a fact in issue. *Downing* held that the "helpfulness" requirement in Rule 702 "implies a quantum of reliability beyond that required to meet a standard of bare logical relevance." *Id.* at 1235.

4. When a court must rule on the admissibility of scientific evidence which is not judicially noticed, it must determine: (1) the soundness and reliability of the process or technique used in generating the evidence, (2) the possibility that admitting the evidence will overwhelm, confuse, or mislead the jury, and (3) the proffered connection between the scientific research or test result to be presented and the particular factual issues in the case. *Id.* at 1237.

5. Even if the Court determines that the data used by the expert is of a type reasonably relied upon by experts in rendering an opinion. It must still address the reliability or general acceptance of an expert's *methodology. DeLuca v. Merrill Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990).

6. In excluding animal evidence as being "not persuasive" in the case of *In re "Agent Orange" Product Liability Litigation,* 611 F. Supp. 1223 (E.D.N.Y. 1985), *aff'd,* 818 F.2d 187 (2d Cir. 1987), *cert. denied sub nom. Lombardi v. Dow Chemical Co.,* 487 U.S. 1234 (1988), the court stated that "there is no evidence that plaintiffs were exposed to the far higher concentrations involved in both the animal and industrial exposure studies. The animal studies are not helpful in the instant case because they involve different biological species. They are of so little probative force and are so potentially misleading as to be inadmissible." 611 F. Supp. at 1241 (citations omitted).

7. In a *Bendectin* case, the first circuit in *Lynch v. Merrell National Laboratories,* 646 F. Supp. 856, (1986) *aff'd,* 830 F.2d 1190 (1st Cir. 1987), stated that "It is also difficult to extrapolate findings from animal studies to human studies because of the large dosage used in the animal studies. . . . [A]lmost any substance can be shown to be teratogenic at some dose in some species." 646 F. Supp. at 865.

8. In *Viterbo v. Dow Chemical Co.,* 826 F.2d 420 (5th Cir. 1987), where plaintiff sought to admit expert testimony based on animal studies that a pesticide caused a variety of ailments, including depression, neurosis and hypertension, plaintiff's expert relied upon a study in which rats exposed to the pesticide developed cancerous tumors and died. The court held the evidence insufficient to provide support for an opinion on causation because the expert acknowledged that the effects of chemicals differ between humans and rats, there was no evidence that plaintiff and the rats received comparable doses, and plaintiff's symptoms were different from those suffered by the rats.

9. In *Selwood v. Oxford Chemicals, Inc.,* No. 90-1048 (M.D. Pa. June 28, 1991), *aff'd,* No. 91-5619 (3d Cir.

February 21, 1992), a pesticide exposure case, Judge Kosik excluded expert testimony premised on animal studies under Rule 702 because those studies are "grossly conjectural" and therefore could not assist the trier of fact.

10. I find that experts in science and medicine rely upon animal studies in determining potential human health effects of exposure to chemicals. Since chemicals cannot be tested on human beings, it is necessary that there be some organism in which scientists can identify the possible doses and the possible adverse effects that might occur in humans if they were to be exposed. However, I further find that experts in science and medicine do not reasonably rely upon animal data to predict causation of human health effects when the data is contradicted by significant epidemiological data in humans.

11. I find that animal studies are of limited reliability when attempting to relate those studies to humans because:

(a) Many test animals are bred to be sensitive to a particular type of response; James T. 91.

(b) Rodent tests are extremely sensitive so they identify a large number of chemicals as carcinogens in animals which are likely not to be carcinogens in humans; James T. 92.

(c) Dose is a major factor, "I mean we are pushing the dose of the chemical until we see a toxic effect." When dealing with humans on the other hand there is always an attempt to limit exposure so there will be no toxic effect. James T. 92-93.

(d) Animals have dramatically different physiology, biochemistry and metabolism pathways that break down the toxic chemicals so that, from species to species, there may be differences in bioactivation and detoxification; James T. 92, 93.

(e) Rats and mice are fed ad libitum, they are allowed to eat as much as they want. They become obese and it has been shown that because they are obese it increases the rate of tumors that have been observed; James T. 93.

(f) Test animals are ordinarily dosed with the chemical under study at the "maximally tolerated dose" which is the highest daily dose that the animal can sustain without having a decrease in body weight of more than ten percent. This may result in "metabolic overload" which refers to feeding test animals such high doses that their detoxification mechanism or physiologic processes are so overwhelmed that an abnormal alteration of metabolism is created and affects may be observed at those high doses which would not be observed at lower doses because the same conditions no longer exist in the animal. James T. 94-96.

12. I find that the use of animal studies data as a basis for an opinion as to causation of adverse health effects in humans when that data is contradicted by significant epidemiological data in humans, is an unreliable use of such data. I find further that such a use of that data would tend to mislead or confuse the jury and would be of no assistance to the jury in deciding the issues in this case.

13. I also find that animal studies of PCBs are not relevant to prove exposure to PCBs or causation of adverse health effects in the Plaintiffs and that such evidence is irrelevant and inadmissible under Rule 402 of the Federal Rules of Evidence.

I therefore issue the following Order:

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

George Burrell, et al. v. *Septa, et al.*	No. 86-2235
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
John Narcise, et al. v. *Septa, et al.*	No. 87-1190
Andre Williams v. *Septa, et al.*	No. 87-1258
Charles Stanbach, et al. v. *Septa, et al.*	No. 87-3227
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269

ORDER

AND NOW, this 21st day of October, 1992, the Defendants' Motion *In Limine* to Exclude Evidence of Animal Studies is GRANTED. Plaintiffs are prohibited from presenting testimony, evidence or statements to the jury concerning or relying upon animal studies to predict causation of human health effects.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.

APPENDIX III-E

IN THE UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS DOCUMENT RELATES TO:

Mabel Brown v. *Septa, et al.*	No. 86-2229
Goerge Burrell v. *Septa, et al.*	No. 86-2235
Wallace Cummins v. *Septa, et al.*	No. 86-2669
K. Louise Jones, et al. v. *Septa, et al.*	No. 86-5277
Christopher Brown, et al. v. *Septa, et al.*	No. 86-7414
Cathlene Brown, et al. v. *Septa, et al.*	No. 86-7415
Craig Brown, et al. v. *Septa, et al.*	No. 86-7416
Margherita Barbetta v. *Septa, et al.*	No. 86-7417
Mary Retta Johnson v. *Septa, et al.*	No. 86-7418
Celeste Brown, et al. v. *Septa, et al.*	No. 86-7419
Clemmon Brown, et al. v. *Septa, et al.*	No. 86-7420
Cloyd Brown, et al. v. *Septa, et al.*	No. 86-7421
Curtis Brown, et al. v. *Septa, et al.*	No. 86-7422
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
Mary Alice Knight v. *Septa, et al.*	No. 87-0712
William Butler, et al. v. *Septa, et al.*	No. 87-2874
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269
William Reid, et al. v. *Septa, et al.*	No. 87-5304

MEMORANDUM

R. F. KELLY, J. October 21, 1992

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AS TO PLAINTIFFS' PERSONAL INJURY CLAIMS

Defendants General Electric Co., Monsanto Co., Westinghouse Electric Corp., Southeastern Pennsylvania Transportation Authority, National Railroad Passenger Corporation, The Budd Co., and the City of Philadelphia have filed a Motion for Summary Judgment as to all of Plaintiffs' personal injury claims. The Plaintiffs involved in this motion are all present or former residents of the neighborhood adjacent to the Paoli Railyard ("the Yard") to distinguish them from plaintiffs who were *employed* at the Yard. This motion concerns a total of eighteen consolidated actions involving thirty-two Plaintiffs or Plaintiffs' decedents (hereinafter "Plaintiffs"), who claimed to have suffered personal injuries as a result of alleged exposure to polychlorinated biphenyls ("PCBs") from the Yard. Plaintiffs seek recovery for, (1) physical injuries caused by PCBs; (2) the increased risk of future illness; (3) fear of emotional distress; (4) the cost of a medical monitoring or surveillance program. Although Plaintiffs have now abandoned their claims for increased risk, they continue to press their claims for recovery on the other three grounds.

In November 1988, this Court granted summary judgment in favor of Defendants on Plaintiffs' personal-injury claims. *In re Paoli R.R. Yard PCB Litigation*, 706 F. Supp. 358 (E.D. Pa. 1988). The Court of Appeals reversed that judgment and remanded the actions for further proceedings. *In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829 (3d Cir. 1990), *cert. denied sub nom. General Elec. Co. v. Knight*, 111 S. Ct. 1524 (1991).

On remand, by Order dated June 4, 1991, we established a discovery schedule that required Plaintiffs to

identify their trial experts and to disclose the substance of those experts' opinions by March 17, 1992. Defendants were required to produce the same information for their trial experts by April 17, 1992. This same Order also allowed the parties to have until June 17, 1992 to depose expert witnesses. At Plaintiffs' request, that deadline was later extended to June 24, 1992. The June 4, 1991 Order also set a firm trial date for August 3, 1992. We severed, and deferred for a later trial, three other actions involving individuals who had worked at the Yard and who asserted claims under the Federal Employers Liability Act.

The list of expert witnesses identified by Plaintiffs in March 1992 was substantially different from those involved in the case at the time of the 1988 summary judgment and appeal. Certain Plaintiffs represented by the Kohn, Nast and Klehr, Harrison law firms (the "Kohn/Klehr Plaintiffs") named three experts on issues relevant to their personal-injury claims: (1) Melvyn Kopstein, Ph.D., was designated to testify about the Paoli residents' "opportunities for exposure" to PCBs from the Yard; (2) Ian C.T. Nisbet, Ph.D., was designated to testify about Plaintiffs' exposure to PCBs; and (3) Janette Sherman, M.D., was designated to testify that Plaintiffs' alleged injuries were caused by their exposure to PCBs and that Plaintiffs require medical monitoring to detect and treat future PCB-related illnesses.

The Plaintiff in *Reid v. Septa, et al.* No. 87-5304 did not designate any expert witness in March 1992 as required by the June 4, 1991 scheduling Order.[1]

In their joint pretrial memorandum filed July 17, 1992, the Kohn/Klehr and Hanes Plaintiffs designated three *additional* trial experts—Deborah Barsotti, Ph.D., Benjamin Calesnick, M.D., and Arthur Zahalsky, Ph.D. Al-

[1] See this Court's memorandum regarding Defendants' Motion to Preclude Expert Testimony of Dr. Harry Shubin.

though those individuals had offered opinions on Plaintiffs' behalf in 1988, they had not been designated as trial experts, nor had the substance of their opinions been disclosed, in accordance with this Court's June 4, 1991, Order. Defendants had deposed Drs. Barsotti and Zahalsky in 1988 (they had never deposed Dr. Calesnick), but they did not depose these individuals during the expert discovery period following the remand of these cases. Plaintiffs' pretrial memorandum also listed as a "fact witness" William J. Nicholson, Ph.D., who in 1988 had offered opinions on Plaintiffs' behalf as a *expert* witness.[2]

By Order dated June 3, 1992, this Court set June 25, 1992, as the deadline for the parties to submit motions *in limine* and dispositive motions. On that date, Defendants filed, *inter alia,* separate motions *in limine* to exclude the opinions of Drs. Kopstein, Nisbet, Sherman, Schecter, and DiGregorio under Federal Rules of Evidence 702, 703, and 403, and the instant motion for summary judgment on Plaintiffs' person-injury claims.[3] On July 28, 29, 30, and 31, and August 3, 1992, this Court conducted an evidentiary hearing on the motions *in limine.* Among Plaintiffs' experts, Drs. Kopstein, Nisbet, and Sherman testified at that hearing. At the conclusion of the hearing, this Court continued the trial date pending disposition of

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[2] See this Court's memorandum regarding Defendants' Motion to Preclude the Testimony of Drs. Calesnick, Barsotti, Zahalsky, Nicholson, and Jenkins.

[3] Defendants also filed motion *in limine* to exclude, and to bar Plaintiffs' experts from testifying about, three categories of evidence: (1) studies purporting to show adverse effects of PCB exposure in animals; (2) evidence concerning the alleged health effects of certain chemicals (including dioxins and dibenzofurans) other than PCBs that are sometimes present in trace amounts in transformer fluid but as to which Plaintiffs have presented no proof of their own exposure; and (3) evidence concerning incidents in Japan and Taiwan (known as "Yusho" and Yu Cheng," respectively) in which large numbers of individuals ingested rice oil that had been contaminated with PCBs and dibenzofurans.

the parties' motions. Those motions have now been decided.

I have excluded the opinion testimony of Janette D. Sherman, M.D. for the reasons set forth in my memorandum re: Motion to Exclude the Opinion Testimony of Janette D. Sherman, M.D. Because of that ruling, the following Kohn/Klehr residential Plaintiffs are without expert testimony with regard to medical causation:

Bessie Cunningham	No. 87-5269
Matthew Cunningham	No. 87-5269
Patricia Ingram	No. 86-7561
John Ingram, Sr.	No. 86-7561
John Ingram, Jr.	No. 86-7561
April Ingram Robinson-Ray	No. 86-7561
Patricia Burrell	No. 86-2235
George Burrell	No. 86-2235
Amber Burrell	No. 86-2235
Monica Hilton	No. 86-2235

Twelve of the Kohn/Klehr Plaintiffs *never* had expert testimony as to medical causation. They are:

Mabel Brown	No. 86-2229
Theresa Butler	No. 87-2874
William Butler	No. 87-2874
Bryan Jackson	No. 87-2874
Wallace Cummins	No. 86-2669
Harvey Jones	No. 86-5277
Louise Jones	No. 86-5277
Mary Alice Knight	No. 87-0712
Allen Simpson	No. 87-2874
Donald Simpson	No. 87-2874
Karen Simpson	No. 87-2874
Marvin Simpson	No. 87-2874

For the reasons set forth in the memorandum relating thereto, I have excluded the opinion testimony of Ian C.T. Nisbet, Ph.D. as to exposure to PCBs. Because of that ruling, five of the Kohn/Klehr Plaintiffs are without expert testimony as to exposure. They are:

Bessie Cunningham	No. 87-5269
Matthew Cunningham	No. 87-5269
Amber Burrell	No. 86-2235
Priscilla Burrell	No. 86-2235
Patricia Ingram	No. 86-7561

Seventeen of the Kohn/Klehr Plaintiffs *never* proffered expert testimony as to exposure to PCBs. They are:

Mabel Brown	No. 86-2229
George Burrell	No. 86-2235
Theresa Butler	No. 87-2874
William Butler	No. 87-2874
Monica Hilton	No. 86-2235
Bryan Jackson	No. 87-2874
Wallace Cummins	No. 86-2669
John Ingram, Jr.	No. 86-7561
John Ingram, Sr.	No. 86-7561
April Ingram Robinson-Ray	No. 86-7561
Harvey Jones	No. 86-5277
Louise Jones	No. 86-5277
Mary Alice Knight	No. 87-0712
Allen Simpson	No. 87-2874
Donald Simpson	No. 87-2874
Karen Simpson	No. 87-2874
Marvin Simpson	No. 87-2874

For the reasons set forth in the memoranda dealing with the motions *in limine* to exclude the testimony of G. John DiGregorio, M.D. and Arnold J. Schecter, M.D., M.P.H., I have excluded their opinion testimony. For that reason, all nine of the Bruce Hanes' Plaintiffs are without expert testimony as to medical causation and exposure to PCBs. Those nine Plaintiffs are:

Cathlene Brown	No. 86-7415
Celeste Brown	No. 86-7419
Christopher Brown	No. 86-7414
Clemmon Brown	No. 86-7420
Cloyd Brown	No. 86-7421

Craig Brown	No. 86-7416
Curtis Brown	No. 86-7422
Mary Johnson	No. 86-7418
Margherita Barbetta	No. 86-7417

For the reasons set forth in the memorandum regarding Defendants' Motion To Preclude Expert Testimony of Harry Shubin, M.D., the Plaintiff in *Reid v. Septa* is without expert testimony as to medical causation and exposure to PCBs.

Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment shall be entered in favor of the moving party where it appears "that there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." The standard for granting summary judgment "mirrors the standard for a directed verdict." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). In response to a motion for summary judgment, the non-moving party cannot simply rest on the assertions in his pleadings; rather, he must make a sufficient showing to establish a genuine issue of fact on those elements with respect to which he has the burden of proof. *Celotex Corp.*, 477 U.S. at 323.

As set forth in the findings of fact and conclusions of law in support of the Orders excluding Plaintiffs' expert testimony, the opinions of Drs. Nisbet, Sherman, Schecter, and DiGregorio are inadmissible under Rules 702, 703, and 403 of the Federal Rules of Evidence.[4] Inadmissible evidence is not properly part of the summary judgment record and cannot create a genuine issue of material fact sufficient to block summary judgment. *See In re Paoli,*

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[4] In addition, as set forth in the relevant findings of fact and conclusions of law, Plaintiffs' evidence regarding animal studies, dioxins and other purported chemical components of transformer fluid, and the Yusho and Yu Cheng incidents is inadmissible and cannot form the basis for expert opinions in these cases.

916 F.2d at 862; *Fowle v. C&C Cola*, 868 F.2d 59, 67 (3d Cir. 1989).

I have not considered the opinions of Drs. Barsotti, Zahalsky, Calesnick, and Nicholson who were not identified as trial witnesses until the Kohn/Klehr and Hanes Plaintiffs filed their joint pretrial memorandum. Plaintiffs knew that they were required to designate their trial experts by March 17, 1992, but they failed to do so. Moreover, Defendants would be seriously prejudiced if they were required to defend against the opinions of the newly identified experts at this late date.

To prove a prima facie case Plaintiffs must establish the following elements: (1) that Defendants released PCBs into the environment; (2) that Plaintiffs somehow ingested those PCBs into their bodies; (3) that Plaintiffs have an injury; and (4) that PCBs are the cause of the injury. *In re Paoli*, 916 F.2d at 860. Plaintiffs have no competent expert evidence on the crucial issues of exposure and causation. Without such expert testimony, Plaintiffs cannot prove elements 2, 3, and 4.

Also in, *In re Paoli*, 916 F.2d at 852 the court indicated its approval of the case of *Merry v. Westinghouse Electric Corp.*, 684 F. Supp. 847 (M.D. Pa. 1988) as follows:

> "We agree with *Merry*, and predict that the Supreme Court of Pennsylvaia would follow the weight of authority and recognize a cause of action for medical monitoring established proving that:
>
> 1. Plaintiff was significantly exposed to a proven hazardous substance through the negligent actions of the defendant.
>
> 2. As a proximate result of exposure, plaintiff suffers a significantly increased risk of contracting a serious latent disease.

3. that increased risk makes periodic diagnostic medical examinations reasonably necessary.

4. Monitoring and testing procedures exist which make the early detection and treatment of the disease possible and beneficial.

These factors would, of course, be proven by competent expert testimony, *see Ayers*, 106 N.J. at 606, 525 A.2d at 312."

There is no reason why the requirement of proof by *competent expert testimony* should be confined to the issue of medical monitoring.

For the foregoing reasons, I enter the following Order:

IN THE UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS DOCUMENT RELATES TO:

Mabel Brown v. *Septa, et al.*	No. 86-2229
Goerge Burrell v. *Septa, et al.*	No. 86-2235
Wallace Cummins v. *Septa, et al.*	No. 86-2669
K. Louise Jones, et al. v. *Septa, et al.*	No. 86-5277
Christopher Brown, et al. v. *Septa, et al.*	No. 86-7414
Cathlene Brown, et al. v. *Septa, et al.*	No. 86-7415
Craig Brown, et al. v. *Septa, et al.*	No. 86-7416
Margherita Barbetta v. *Septa, et al.*	No. 86-7417
Mary Retta Johnson v. *Septa, et al.*	No. 86-7418
Celeste Brown, et al. v. *Septa, et al.*	No. 86-7419
Clemmon Brown, et al. v. *Septa, et al.*	No. 86-7420
Cloyd Brown, et al. v. *Septa, et al.*	No. 86-7421
Curtis Brown, et al. v. *Septa, et al.*	No. 86-7422
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
Mary Alice Knight v. *Septa, et al.*	No. 87-0712
William Butler, et al. v. *Septa, et al.*	No. 87-2874
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269
William Reid, et al. v. *Septa, et al.*	No. 87-5304

ORDER

AND NOW, this 21st day of October, 1992, Summary Judgment is hereby entered in favor of all Defendants against all Plaintiffs in the above captioned matter.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.

APPENDIX IV-A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

Christopher S. Brown, et al. v. *Septa, et al.*	No. 86-7414
Cathlene Brown, et al. v. *Septa, et al.*	No. 86-7415
Craig Brown, et al. v. *Septa. et al.*	No. 86-7416
Margherita Barbetta, v. *Septa, et al.*	No. 86-7417
Celeste Brown, et al. v. *Septa, et al.*	No. 86-7419
Mary Retta Johnson, v. *Septa, et al.*	No. 86-7418
Clemmon Brown, et al. v. *Septa, et al.*	No. 86-7420
Cloyd H. Brown, et al. v. *Septa, et al.*	No. 86-7421
Curtis Brown, et al. v. *Septa, et al.*	No. 86-7422

MEMORANDUM

R. F. KELLY, J. October 21, 1992

MOTION IN LIMINE TO EXCLUDE THE TESTIMONY OF DR. ARNOLD J. SCHECTER, M.D.

Defendants moved to preclude the testimony of Plaintiffs' expert Arnold J. Schecter, M.D. on the grounds that Dr. Schecter's testimony lacks the requisite factual foundation and the application of reliable scientific methodology for admissibility under Rules 702 and 703 of the Federal Rules of Evidence. Defendants also argue that Dr. Schecter fails to quantify Plaintiff's alleged increased risk of future illness as required under Pennsylvania law.

From the pleadings, depositions and arguments of counsel, I make the following:

FINDINGS OF FACT

1. On June 4, 1991, this Court directed that Plaintiffs designate all trial expert witnesses and provide Defendants with the substance of their testimony and the basis of their opinions at the time of designation in accordance with Rule 26(b)(4) by March 17, 1992.

2. In compliance with that Order, Plaintiffs designated Dr. Arnold J. Schecter as an expert witness and provided his report dated March 16, 1992. In that report, he opined that exposure to PCBs and related chemicals caused certain adverse health effects and that Plaintiffs have reasonable fear of adverse health effects as a result of exposure to PCBs and "coexisting chemicals."

3. At the court hearing on this motion, counsel for Plaintiffs withdrew Dr. Schecter as an expert for the purpose of testifying that Plaintiffs have an increased risk of adverse health effects stating "he may be proffered at time of trial to testify that the Plaintiffs' fear of harm is reasonable . . . ." July 28, 1992 Hearing at 184.

4. Dr. Schecter is offered therefore as an expert witness only as to Plaintiffs' allegation that they suffer from psychological ailments, *i.e.*, fear of future adverse health effects as a result of PCB exposure. July 28, 1992 Hearing at 167-68, 185-86.

5. Dr. Schecter admitted during his deposition that he is unable to offer any opinion as to whether any Plaintiff actually has a fear of future illness or other form of emotional distress. Schecter Dep. 146-47.[1] Dr. Schecter is able to say only that if Plaintiffs do in fact have any such fears, then those fears are reasonable. Schecter Dep. 29; Dr. Schecter's Report.

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[1] Schecter Dep. refers to the deposition of Dr. Arnold J. Schecter taken on June 9 and 10, 1992.

6. Dr. Schecter admitted that he cannot quantify Plaintiffs' risk of contracting future illnesses and does not know the difference, if any, between any Plaintiff's risk of future illness and that of the general population. Schecter Dep. 69-70.

7. Dr. Schecter did not meet Plaintiffs, did not talk to Plaintiffs, did not talk to Plaintiffs' physicians, and did not conduct physical or psychological examinations of Plaintiffs. Schecter Dep. 101-02, 104-05, 147. The sole basis for Dr. Schecter's testimony about any of these plaintiffs is a single conversation with Plaintiffs' counsel during which Plaintiffs' counsel selected and read to Dr. Schecter certain unspecified portions of the deposition testimony of certain unknown Plaintiffs. Schecter Dep. 15, 101-02. Dr. Schecter also refers to reviewing reports in the scientific literature that PCB exposure causes certain illnesses in laboratory animals and that PCBs are believed to cause these illnesses in human populations. Schecter Dep. 34; Dr. Schecter's Report.

8. Dr. Schecter testified that his routine methodology in evaluating his patients includes obtaining complete medical histories, conducting physical examinations, and performing various tests as needed. Schecter Dep. 117-18. In reaching his opinions for this litigation, Dr. Schecter did not follow that stated methodology. Schecter Dep. 147.

9. Because Dr. Schecter cannot quantify or describe in any way the extent of Plaintiffs increased risk of future illnesses, if any, he cannot opine as to the reasonableness of any fears that might be held by Plaintiffs.

10. Whether damages should be awarded for *fear* of future illness is directly related to the issue of *risk* of future illness. If Dr. Schecter cannot quantify the extent of Plaintiffs' increased risk of future illnesses, he may not give his opinion as to the reasonableness of Plaintiffs' fear of such future illnesses.

CONCLUSIONS OF LAW

1. In order to evaluate the admissibility of Dr. Schecter's testimony, this Court has conducted an *In Limine* Evidentiary Hearing as contemplated by *United States v. Downing*, 753 F.2d 1224 (3d Cir. 1985). A record has been produced that is sufficient to evaluate Dr. Schecter's proposed testimony under Rule 702 and 703 of the Federal Rules of Evidence.

2. Rule 702 of the Federal Rules of Evidence ("Rule 702") provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702.

3. Rule 702 authorizes the admission of expert testimony so long as it is (1) rendered by a qualified expert and (2) helpful to the trier of fact. *DeLuca v. Merrill Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 954 (3d Cir. 1990). The helpfulness requirement contains the proposition that expert testimony that is based on unreliable methodology is unhelpful and therefore excludable. *DeLuca*, 911 F.2d at 954.

4. Rule 703 of the Federal Rules of Evidence ("Rule 702") focuses on the reliability of the facts of data upon which the expert has based his opinion. Rule 703 provides:

> The facts or other data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by the experts in a particular field

> in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Fed. R. Evid. 703.

5. Both Rule 702 and Rule 703 require that expert testimony be supported by an adequate factual foundation. *In re "Agent Orange" Product Liability Litigation*, 611 F. Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987), *cert. denied sub nom. Lombardi v. Dow Chemical Co.*, 487 U.S. 1234 (1988).

6. Dr. Schecter admitted at his deposition that he cannot quantify Plaintiffs' risk of contracting future illnesses and does not know the difference, if any, between any Plaintiff's risk of future illness and that of the general population. If Dr. Schecter cannot answer the foregoing questions then he has no basis for an opinion as to the reasonableness of Plaintiffs' fear of future ill health. Dr. Schecter's opinion as to the reasonableness of Plaintiffs' fears is nothing more than an empty conclusion.

7. The lack of any factual foundation renders Dr. Schecter's opinion as to the reasonableness of Plaintiffs' fears unreliable and completely speculative. Under Pennsylvania law, "[U]nless there is a legally significant foundation for a plaintiff's increased risk of harm, a determination of damages for a plaintiff's fear becomes subjective. There must be some basis upon which a plaintiff's fear can be determined to be *reasonable*." *Sutcliffe v. G.A.F. Corp.*, 15 Phila. 339, 346 (1987). As in the *Sutcliffe* case, Plaintiffs' expert can offer no reasonable quantification of the increased risk of harm, if any, suffered by any of the Plaintiffs in this litigation. Therefore, there is no factual basis upon which Dr. Schecter can base his conclusion that Plaintiffs' fears are reasonable.

I therefore issue the following Order:

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

Christopher S. Brown, et al. v. *Septa, et al.*	No. 86-7414
Cathlene Brown, et al. v. *Septa, et al.*	No. 86-7415
Craig Brown, et al. v. *Septa, et al.*	No. 86-7416
Margherita Barbetta v. *Septa, et al.*	No. 86-7417
Mary Retta Johnson v. *Septa, et al.*	No. 86-7418
Celeste Brown, et al. v. *Septa, et al.*	No. 86-7419
Clemmon Brown, et al. v. *Septa, et al.*	No. 86-7420
Cloyd H. Brown, et al v. *Septa, et al.*	No. 86-7421
Custis Brown, et al. v. *Septa, et al.*	No. 86-7422

ORDER

AND NOW, this 21st day of October, 1992, upon consideration of Defendants' Motion *In Limine* to Exclude the Testimony of Dr. Schecter, Plaintiff's response thereto, the record and oral arguments of counsel, it is hereby ORDERED that said Motion is GRANTED. I conclude that Dr. Schecter did not follow a reasonable methodology in reaching his diagnoses, that his opinions were not based on any factual foundation and that he did not rely on data of a type reasonably relied upon by experts in the field when forming his opinions. Dr. Schecter's testimony is hereby excluded from the trial of this case under Rules 702 and 703 of the Federal Rules of Evidence.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.

APPENDIX IV-B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master Docket No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS DOCUMENT RELATES TO ALL CASES

ORDER

AND NOW, this 21st day of October, 1992, upon consideration of Defendants' Motion *In Limine* to Exclude the Testimony of Plaintiffs' Expert, Melvyn Kopstein, Ph.D., all responses thereto, and a hearing on said matter, it is hereby ORDERED that said Motion is DENIED. This Court shall permit Dr. Kopstein to testify regarding Plaintiffs' "opporunities for exposure" to PCBs. Therefore, his testimony shall not be excluded on this basis.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.

APPENDIX IV-C

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master Docket No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

George Burrell, et al. v. *SEPTA, et al.*	No. 86-2235
John Ingram, et al. v. *SEPTA, et al.*	No. 86-7561
Andre Williams v. *SEPTA, et al.*	No. 87-1258
Matthew Cunningham, et al. v. *SEPTA, et al.*	No. 87-5269

MEMORANDUM

R.F. KELLY, J. October 21, 1992

This is a toxic tort case brought by individuals who maintain that they have developed various illnesses as a result of their alleged exposure to polychlorinated biphenyls ("PCBs") from having either worked in or lived adjacent to the Paoli Railyard in Paoli, Pennsylvania. This Court held hearings on July 28, 29, 30, 31 and August 3 and 7, 1992 eliciting testimony and argument on the numerous motions *in limine* and dispositive motions filed in this action.

MOTION IN LIMINE TO EXCLUDE RESULTS OF ANALYSES PERFORMED BY ELI ECO LOGIC LABORATORIES, INC.

Defendants have filed this Motion *In Limine* to exclude all testimony concerning the results of PCB cogener specific analyses of six Plaintiffs performed in May of 1992 by ELI Eco Logic Laboratories, Inc. ("Eco Logic"). Defendants argue that the Eco Logic analyses should be excluded because the results are scientifically unreliable and not data which is reasonably relied upon by experts in the field.

In support of its motion, Defendants presented the testimony of James C. Peterson, Ph.D. ("Dr. Peterson") and his affidavit. Defendants moved into evidence the deposition of Ian C.T. Nisbet, Ph.D. ("Dr. Nisbet") who based many of his opinions on the Eco Logic analyses. In response to Defendants' motion, Plaintiffs presented the testimony and affidavit of Richard F. Gierczak ("Mr. Gierczak") who is an employee of Eco Logic. Plaintiffs also presented the testimony of Dr. Nisbet.

Upon consideration of Defendants' Motion *In Limine* to Exclude the Results of Analyses Performed by Eco Logic, all responses thereto, the hearing and deposition testimony presented to this Court, and all exhibits admitted into evidence at the hearing, this Court makes the following Findings of Fact and Conclusions of Law:

FINDINGS OF FACT

1. Plaintiffs offered Dr. Nisbet as an expert in assessing the exposure of Plaintiffs to PCBs. Dr. Nisbet concluded that several of the Plaintiffs "were sufficiently exposed [to PCBs from the Paoli Rail Yard] . . . to lead to the expectation that they would suffer adverse health effects as a result of [th]eir exposure." March 16, 1992 Report of Dr. Nisbet at 2, 6 (Attached as Exhibit 12 to Defendants' *in limine* Exhibit 22) ("Nisbet Report").

2. Dr. Nisbet's opinion is based in part upon back-calculations that he performed of the 1992 Eco Logic results. July 30, 1992 Hearing Testimony of John Whysner, Ph.D. ("Whysner T") at 23; July 30, 1992 Hearing Testimony of Dr. Nisbet ("Nisbet T.") at 86. In May of 1992, six Plaintiffs' PCB blood levels were tested by Eco Logic which is located in Canada. Whysner T. 22. Dr. Nisbet estimated Plaintiffs' PCB blood levels as of 1986 based upon back-calculations of Plaintiffs' 1992 PCB blood levels recorded by Eco Logic. Nisbet T. 86-87, 102.

3. At the *in limine* hearing, Defendants presented the testimony of Dr. Peterson in support of its motion to exclude the analyses performed by Eco Logic. July 29, 1992 Hearing Testimony of Dr. Peterson ("Peterson T.").

4. Dr. Peterson received his bachelor's degree in Chemistry from North Park College, Chicago, Illinois in 1972. Peterson T. 185. He received a Ph.D. in Analytical Chemistry from the University of Maryland in 1980. Dr. Peterson did his post-doctoral training in Analytical Chemistry at Ecole Polytechnique in France from 1980 to 1982. *Id.*

5. After this training, Dr. Peterson was Supervisor of the Virginia Division of Consolidated Laboratory Services in Richmond, Virginia which is an organization that analyzes trace organics in all types of environmental samples using mostly gas chromatography/mass spectrometry. *Id.*

6. In 1985, Dr. Peterson became Director of Research and Development at Pacific Toxicology Laboratories in Los Angeles, California and has continued in that position for the past seven years. *Id.* at 186. His responsibilities as Director of Research and Development include ensuring that the technical aspects of the laboratory are functioning properly, developing methodologies for gas chromatography/mass spectrometry and gas chromatography/

electron capture analyses, training technologists in the performance of those methodologies and reviewing laboratory results. *Id.* at 186-87.

7. Dr. Peterson routinely analyzes serum samples in adipose tissue for the presence of PCBs in his employment with Pacific Toxicology Laboratories. *Id.* He has analyzed or supervised the analyses of over 30,000 samples for the presence of PCBs. *Id.* Approximately 500 of the 30,000 samples were analyzed by the congener specific analysis. *Id.* at 188.

8. Defendants offered Dr. Peterson as an expert in Analytical Chemistry. Plaintiffs did not challenge Dr. Peterson's qualifications. *Id.* at 188.

9. Dr. Peterson reviewed the depositions of Dr. Nisbet and two Eco Logic employees, Mr. Resch and Mr. Gierczak, and the materials produced by Eco Logic which included information regarding the analytical procedure employed and the data itself. *Id.* at 188-89. Dr. Peterson spent approximately 12 hours reviewing Eco Logic's analytical procedures and the data itself. *Id.* at 189.

10. At the *in limine* hearing, Plaintiffs presented the testimony of Mr. Gierczak in response to Defendants' Motion to Exclude the Analyses Performed by Eco Logic. July 31, 1992 Hearing Testimony of Mr. Gierczak ("Gierczak T.").

11. Plaintiffs offered Mr. Gierczak as an expert in Analytical Chemistry. Defendants challenged Mr. Gierczak's qualifications. Gierczak T. 158.

12. Mr. Gierczak obtained a bachelor's degree in 1984 and master of science degree in Medical Sciences in 1988 from McMaster University in Hamilton, Ontario. *Id.* at 152. In connection with obtaining his master's degree, Mr. Gierczak did original research which involved looking at the metabolism of a specific equine estrogen. *Id.* at 153. Mr. Gierczak is currently an employee of Eco Logic and has worked at Eco Logic for about two and half

years. *Id.* at 154-55. Eco Logic is a scientific consulting firm. *Id.* at 155. About 90% of the work that Mr. Gierczak performs for Eco Logic is litigation-related. *Id.* at 188.

13. Mr. Gierczak's formal training in Analytical Chemistry consists of courses that he took as an undergraduate. *Id.* at 241. He has analyzed approximately 50 samples using the PCB congener specific analysis for the purposes of "method development." *Id.* at 189-90. Eco Logic's report in this case of the six Plaintiffs' PCB blood levels was the first report ever issued regarding PCB congener specific analyses of human blood samples. *Id.* at 190-92.

14. On his curriculum vitae, Mr. Gierczak listed the World Health Organization as recent client experience. However, he admitted that the World Health Organization was only a resource and that Eco Logic did not "do anything for the World Health Organization." *Id.* at 200-02.

15. Plaintiffs' blood samples were received by Eco Logic on or about March 13, 1992. Eco Logic reported the results of its analyses performed on these samples three months later on June 15, 1992. *Id.* at 209.

16. Eco Logic failed to provide a written laboratory protocol describing the technique that was performed. Peterson T. 189-90. A written laboratory protocol is a "step-by-step explanation to the technologist performing the test, how to perform the test in great detail. It also includes the extraction process, clean-up, preparation of the samples, the analytical instrumentation procedures, as well as quality assurance requirements to perform the test." *Id.* at 190. The purpose of having a written laboratory protocol is to ensure that the analysis is performed the same way each time. *Id.* at 192-93. Also, the written protocol is used by outside scientists or analytical chemists to review the results and evaluate the data. *Id.* at

193. Dr. Peterson stated that a written laboratory protocol is something that every reliable laboratory would have. *Id.* at 190. It is accepted practice to have such a protocol, and a written laboratory protocol is essential, particularly in a complex analysis. *Id.* at 192.

17. Congener specific analysis of PCBs is the most complex analytical chemistry procedure that Dr. Peterson has encountered. *Id.* at 190. It takes approximately six or seven days to perform this type of analysis. *Id.* at 191-92. There are many different PCB components which are called "congeners" in a human blood sample or an environmental PCB mixture. The congener specific analysis is a technique in which individual congeners of a PCB mixture are quantitated and reported. *Id.* at 187-88.

18. In response to requests for a written description of the technique that Eco Logic used in performing its analyses of Plaintiffs' blood samples, Eco Logic eventually provided to Defendants a brief summary of the steps taken in the analytical process. *Id.* at 193. "But it wouldn't qualify as a written laboratory protocol as such, which would be used in a laboratory." *Id.* The summary included about one page concerning sample extraction and clean-up and approximately six pages of analytical instrumentation descriptions. *Id.* Mr. Gierczak acknowledged that Eco Logic did not have a written laboratory protocol for the performance of PCB congener specific analyses. Gierczak T. 160. Mr. Gierczak referred during his testimony to a laboratory notebook that is used at Eco Logic which summarizes various steps performed on samples at the laboratory beginning from the time samples are received. *Id.* at 161-62.

19. Mr. Gierczak cited three references for the method used by Eco Logic in performing the analyses of Plaintiffs' blood samples: Berse; Swackhammer; and EPA method 680. Peterson T. 193-94. At his deposition, Mr. Gierczak referred to the Berse paper as the method he followed in performing the analyses. *Id.* at 194.

20. After reviewing the laboratory documents and chromatograms, Mr. Peterson stated that Mr. Gierczak made several deviations from the technique described in the Berse paper. There were several deviations in terms of the clean-up process and the Berse paper was not followed much after the extraction process. *Id.*

21. Eco Logic produced two sets of printouts of data. Gas chromatography/mass spectrometry ("mass spectrometry") and gas chromotography/electron capture analysis ("electron capture analysis") are the two analytical techniques employed by Eco Logic. *Id.* at 187, 195.

22. Electron capture analysis is often used to analyze PCBs because the detector responds well to chlorinated substances but this method does not provide as much qualitative information as mass spectrometry which also responds well to PCBs. *Id.* at 196. The basic process for measuring a compound is quite different between mass spectrometry and election capture analysis. *Id.* at 196-97.

23. The purpose of quality assurance is that it basically validates the analysis performed. Quality assurance tells the analyst and other persons reviewing the data that it is reliable. *Id.* at 198. Mr. Peterson stated that quality assurance is "absolutely essential" for the type of analysis involved in this case. *Id.* Every analytical technique and every piece of data requires quality assurance in order to validate its accuracy. *Id.* at 198-99. "In the quality assurance procedures, you generate data, which tells you that what you're measuring is correct. The identity of those compounds and the levels which you have measured is correct." *Id.* at 199.

24. Mr. Gierczak identified an Eco Logic booklet entitled "Quality Assurance, Quality Control Manual for the Analysis of Trace Organic Compounds" which he admitted was "put together . . . for the subpoena" after the analyses on Plaintiffs' samples were performed. Gierczak T. 232. Mr. Gierczak stated that prior to the subpoena, this booklet existed in maybe two or three pieces. *Id.*

25. The use of lab blanks is one example of a quality assurance procedure. A lab blank is used in order to determine what the background level is for the analyte that you are measuring. Peterson T. 199. Eco Logic used blank water in this case. Eco Logic carried the water through the analytical process, analyzed it with the same instrumentation as Plaintiffs' samples and looked for the presence of PCBs in that blank sample. *Id.* Dr. Peterson testfied that this is a standard laboratory technique. *Id.* Eco Logic found PCBs in the laboratory blank which Dr. Peterson stated that this in itself is not unusual. He stated that the PCBs could have come from a variety of sources, for example, "[t]he equipment, the glassware, the water itself, it's difficult to determine, but, it's introduced by the laboratory, in some manner." *Id.* at 200. Eco Logic ran only one laboratory blank in this case. *Id.* at 200-01, 217.

26. The level of PCBs in the laboratory blank was 3 parts per billion. *Id.* at 218. Eco Logic's "Qality Control Manual" states that "[b]lanks are used to determine if there's a significant contribution of analyte to the sample extract from sources other than the sample" and that "[a] significant result may suggest contamination from the laboratory, in which case, the cause must be located and corrected." Gierczak T. 235-36. Mr. Gierczak stated that the PCBs in the blank could have been introduced into the water but these PCBs did not come from Plaintiffs' samples. *Id.* at 240. He also admitted that he testified at his deposition that "there [was] no evidence" of "background laboratory contamination." *Id.* at 235.

27. Mr. Gierczak testified that it is misleading to compare only total PCB concentrations in the samples with the levels of PCBs found in the laboratory blank. He stated that "I think you need to look at the individual congeners to show really what's going on behind the scenes." *Id.* at 179. However, Mr. Gierczak admitted that, in regard to the specific congeners employed by Dr. Nisbet in performing his back-calculations, the levels found

in the laboratory blank exceeded the values reported for at least one Plaintiff. *Id.* at 239. The laboratory blank revealed 1.3 parts per billion of PCBs compared to levels found in Plaintiff Amber Burrell of 1.2 parts per billion. *Id.* This level of background contamination is "almost indistinguishable" from the levels reported in Plaintiff Amber Burrell's blood sample. Peterson T. 217-18.

28. Mr. Gierczak acknowledged that Eco Logic did not run the "vacutainer blanks," which were described in his initial report which was faxed to Dr. Nisbet, and that only one of the three matrix spike duplicates identified in this report had been analyzed. Gierczak T. 210-11.

29. A surrogate spike involves adding a compound to the sample which is very close in its characteristics to the analytes that are to be measured. The surrogate spike is used as a means of determining how the analytical process measured the analytes of that particular sample. Peterson T. 202. A matrix spike involves taking blank blood and spiking it with all the analytes that are to be measured. This spike sample is analyzed and the results are compared to the actual amount of the analyte that was added to the blank blood sample. *Id.* at 203.

30. A recovery rate compares the difference between the amount of the analytes actually measured in your spiked sample and the amount actually added to that sample. *Id.* at 204. Dr. Peterson stated that the matrix spike recovery rate should equal the surrogate recovery rate. *Id.* The recovery rates of the spikes analyzed by Eco Logic were not the same. "The surrogates were recovered at about 50 percent, while the matrix spikes were recovered at 100 percent." *Id.* Dr. Peterson testified that this inconsistency indicates a problem in Eco Logic's quantitation. *Id.* at 204-05.

31. In addition, Dr. Peterson stated that the levels at which the surrogate spikes and the matrix spikes were measured were extremely too high. These levels were

much higher than the levels Eco Logic ultimately generated as the level of PCBs in Plaintiffs' blood samples. *Id.* at 205.

32. Dr. Peterson testified that there was no quality assurance data provided for the results obtained by mass spectrometry. *Id.* at 215. There were no matrix or surrogate spike samples analyzed by mass spectrometry. *Id.* Dr. Peterson stated that "[i]n absence of [this] recovery data, I don't think you can be confident in the results here." *Id.* at 216.

33. A calibration range is the range of concentrations of your standards with which you calibrate your instruments. *Id.* at 206. Standard solutions are prepared, injected into the instrument and analyzed to assess the response of the instrument for that level of concentration. *Id.* at 240. Response factors are established for the various analytes on the instrument for that particular day. *Id.* at 206. The purpose of calibrating instruments is to ensure that quantitation is done accurately. Dr. Peterson stated that a range is established according to what the range of the actual analytes to be measured is anticipated to be. *Id.* at 207.

34. The results of the analyses performed on Plaintiffs' samples by Eco Logic did not fall within the calibration range which was set up for the testing by the electron capture analysis. *Id.* "[A]ll of the calibration standards were higher than any of the analyte concentrations which were measured." *Id.* The calibration range was at times higher by a factor of two and at other times higher by a factor of 100. *Id.* at 208. Mr. Gierczak testified that some of the PCB congeners came very close to falling within the calibration range. Gierczak T. 219. "Well, they fall in the estimation of Eco Logic, well within the calibration table, the linear range of the calibration table." *Id.* at 186. However, Mr. Gierczak admitted that "not one" of the PCB congeners that he analyzed

actually fell within the five point calibration range. *Id.* at 219-20.

35. A calibration range was also set up for the mass spectrometry data. Dr. Peterson testified that "[t]he concentrations measured in the real samples fell below the calibration range in the mass spectrometer." Peterson T. 208.

36. Dr. Peterson testified regarding the importance of having a calibration range which encompasses the levels measured in the actual samples especially at the low levels measured in this case. "[I]t will affect your accuracy because you're not really sure how the instrument behaves at the very low levels, because you have no standards which have been run at that level." *Id.* at 209. Dr. Peterson stated that the effect of having sample results which fall outside the calibration range is that it makes Eco Logic's results "less accurate." *Id.*

37. In electron capture analysis, a laboratory typically uses two columns. The first column is the analytical column ("DB5 column") which is where the quantitation takes place. *Id.* at 210. The second column is the confirmation column ("DB17 column") which is the column that is basically run to confirm the identities of the individual congeners analyzed. *Id.* Dr. Peterson testified that it is essential to compare peak-by-peak the peaks on the DB5 column to the peaks on the DB17 column. *Id.* at 211. Dr. Peterson stated that a confirmation column is required in this type of analysis because if such a column is not used there is a great possibility of "misidentifying the individual congeners, not only as PCBs, but also misidentifying them as some other compounds." *Id.* Dr Peterson testified that it is extremely possible that compounds other than PCBs are reported in the Eco Logic results. *Id.* at 212. Moreover, there is a high likelihood that some of the congeners are misidentified with respect to what congeners they are or with respect to other chemicals that may have been in the blood. *Id.* at

214. Dr. Peterson testified that he had little confidence that the identifications were correct due to the lack of confirmation. *Id.* at 219.

38. Mr. Gierczak admitted that the purposes of the DB17 column is to prevent the potential misidentification of another compound. Gierczak T. 217. In addition, in his affidavit which was submitted with his testimony at page three, Mr. Gierczak stated that the DB17 column is "absolutely critical to the overall analysis." Eco Logic's "Quality Control Manual" states that "the presence of an analyte is confirmed only when identified on both columns." *Id.* at 233. However, Mr. Gierczak was unable to state whether any of the 15 PCB congeners listed in his affidavit had been identified on the DB17 column or on the mass spectrometer. *Id.* at 215-16.

39. There are certain congeners that appeared in both the mass spectrometry results and the electron capture analysis results. *Id.* at 216. For example, PCB 118 was run by both of these methods. However, the results on PCB 118 differed between these two methods by a factor of two, almost three. *Id.* at 216-17. Dr. Peterson stated that this inconsistency points to a problem in the accuracy of the analyses. *Id.* at 217.

40. When Dr. Nisbet was shown Eco Logic's results from the DB17 column at the *in limine* hearing, he was unable to locate congeners 180, 118, 205 and 206 on the DB17 column even though he relied upon the presence of these congeners in performing his back-calculations. Nisbet T. 128-30. These congeners are not found on Eco Logic's DB17 column results. *Id.* at 127-30. Mr. Gierczak testified that he knew of no other print-out from the DB17 column. Gierczak T. 229-30. Dr. Nisbet stated that he did not use Eco Logic's confirmation because he had not seen it at the time that he did his back-calculations. Nisbet T. 130. Dr. Nisbet testified that he confirmed the presence of specific congeners only from the chromatograms. *Id.* at 129. However, he then agreed

that one could not confirm a peak on a DB17 column with a peak on a DB5 column by merely looking at the chromatograms. *Id.* at 131.

41. Dr. Peterson testified that he considered the data produced by Eco Logic on the six Plaintiffs to be unreliable. Peterson T. 220. He also stated that he would not feel comfortable allowing data such as that produced by Eco Logic to be released from Pacific Toxicology Laboratories. *Id.* at 219-20.

CONCLUSIONS OF LAW

1. In cases involving proffers of scientific evidence, the Third Circuit stated that "[i]t would appear that the most efficient procedure that the district court can use in making the reliability determination is an *in limine* hearing." *United States v. Downing,* 753 F.2d 1224, 1241 (3d Cir. 1985). The court went on to state that "[i]n the course of the *in limine* proceeding, the trial court may consider, *inter alia,* offers of proof, affidavits, stipulations, or learned treatises . . . in addition to testimonial or other documentary evidence (and, of course, legal argument)." *Id.*

2. This Court has before it a developed record and specific findings regarding reliability issues. *In re Paoli R.R. Yard PCB Litigation,* 916 F.2d 829, 858 (3d Cir. 1990), *cert. denied sub nom. General Elec. Co. v. Knight,* 111 S. Ct. 1524 (1991). This Court has made a factual inquiry and finding as to what data experts in the field find reliable. *In re Japanese Electronic Products Antitrust Litigation,* 723 F.2d 238, 277 (3d Cir. 1983), *rev'd on other grounds sub nom. Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574 (1986).

3. The Federal Rules of Evidence embody a strong preference for admitting evidence that has some potential of assisting the jury. *DeLuca v. Merrell Dow Pharmaceuticals, Inc.,* 911 F.2d 941, 956 (3d Cir. 1990).

4. The hearings held by this Court relating to Defendants' Motion *In Limine* to Exclude Results of Analyses Performed by Eco Logic have produced a sufficient record to evaluate this evidence under Federal Rules of Evidence 702 and 703.

I. EXCLUSION BASED UPON RULE 702

5. Rule 702 of the Federal Rules of Evidence ("Rule 702") provides that:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702.

6. "Rule 702 authorizes the admission of expert testimony so long as it is rendered by a qualified expert and is helpful to the trier of fact." *DeLuca,* 911 F.2d at 954 (citations omitted).

7. Rule 702's helpfulness requirement implicitly contains the proposition that expert testimony that is based upon unreliable methodology is unhelpful and thus excludable. *DeLuca,* 911 F.2d at 954.

8. The focus of the Rule 702 inquiry is on the reliabiliy of the methodology employed by the expert in reaching his or her conclusions. *Paoli,* 916 F.2d at 856-57; *Downing,* 753 F.2d at 1238.

9. If a reliable methodology was "so altered as to skew the methodology itself, *Downing* would be the appropriate vehicle for evaluation" but not if the challenged procedure was an application of an accepted methodology. *Paoli,* 916 F.2d at 858 (citing *DeLuca,* 911 F.2d at 955 n.15).

10. *Downing* requires a district court to conduct a preliminary inquiry focusing on:

(1) the soundness and reliability of the process or technique used in generating the evidence,

(2) the possibility that admitting the evidence would overwhelm, confuse, or mislead the jury, and

(3) the proffered connection between the scientific research or test result to be presented, and particular disputed factual issues in the case.

753 F.2d at 1237.

11. The reliability inquiry is flexible. The court may examine a variety of factors in addition to scientific evidence in assessing reliability of a particular technique or methodology. *Downing,* 753 F.2d at 1238. For example, the court may examine the expert's technique in relation to more established modes of scientific analysis and the existence of specialized literature dealing with the expert's technique or methodology. Other factors include: the non-judicial uses to which the scientific technique are put; the qualifications of the expert witness; and the frequency with which the methodology or technique leads to erroneous results. *Id.* at 1239.

12. After assessing the reliability of an expert's methodology, the court must determine whether admitting the evidence would overwhelm, confuse or mislead the jury. *See DeLuca,* 911 F.2d at 957.

13. "This inquiry focuses on the extent to which probative scientific evidence is capable of being properly utilized by the jury . . . ." *Id.*

14. The touchstone of Rule 702 is the "helpfulness of the expert testimony, *i.e.,* whether it 'will assist the trier of fact to understand the evidence or to determine a fact in issue.' " *Downing,* 753 F.2d at 1235 (quoting Fed. R. Evid. 702).

15. Helpfulness turns on whether the expert's methodology is sufficiently reliable so that it will aid the jury in reaching accurate conclusions. *DeLuca,* 911 F.2d at 956 (citation omitted).

16. Where the record and factual findings demonstrate that the expert used an unreliable scientific mode of analysis and thus obtained "inaccurate results" from this analysis, the court must exclude the proffered testimony pursuant to Federal Rule of Evidence 702. *See Paoli,* 916 F.2d at 857.

17. Defendants argue that Mr. Gierczak is not qualified under Rule 702 to testify as an expert in analytical chemistry or congener specific analysis.

18. Rule 702 should be interpreted liberally. *Paoli,* 916 F.2d at 855. However, an expert must demonstrate special competence to present expert testimony. *Id.* at 862 (citation omitted). Based upon all the evidence presented, I find that Mr. Gierczak lacks the "knowledge, skill, experience, training or education" necessary to qualify him as an expert in either analytical chemistry or analyzing human blood samples by congener specific analysis. In terms of his experience and skill, this is the first report that Mr. Gierczak has issued concerning the congener specific analysis of human blood for PCBs. Findings of Fact ("FF") ¶ 13. Relating to his training and education, Mr. Gierczak's undergraduate courses in analytical chemistry do not qualify him as an expert in this field. *Id.* Plaintiffs have failed to establish Mr. Gierczak's "special competence" that is required under Rule 702 in order to testify as an expert.

19. Defendants also argue that Eco Logic altered an accepted methodology to such a point as to render Eco Logic's methodology unreliable under Rule 702.

20. Dr. Peterson testified that a confirmation column is required in this type of analysis because if such a column is not used there is a great possibility of mis-

identifying the individual congeners. FF ¶ 37. He stated that it is extremely possible that compounds other than PCBs are reported in the Eco Logic results. Dr. Peterson testified that he had little confidence that the identifications were correct due to the lack of confirmation. *Id.* Mr. Gierczak admitted that the purposes of the DB17 column is to prevent the potential misidentification of another compound. FF ¶ 38. In addition, he stated that the DB17 column is "absolutely critical to the overall analysis." *Id.* Mr. Gierczak was unable to state whether any of the 15 PCB congeners listed in his affidavit had been identified on the DB17 column or on the mass spectrometer. *Id.*

21. Dr. Peterson testified that Eco Logic failed to perform steps that are essential to the type of analyses it employed which included: failure to provide a written laboratory protocol describing the congener specific analyses performed; failure to provide adequate quality assurance data; failure to perform proper analytical and quantitative methods; failure to establish a sufficient calibration range; and failure to confirm all identifications using data from the DB17 column. FF ¶¶ 16, 18-31, 33-38. The potential for erroneous or inaccurate results was shown by Dr. Peterson to be extremely likely. FF ¶¶ 30, 32, 33-37, 39.

22. I find that Dr. Peterson is well qualified under Rule 702 to evaluate analyses employed by Eco Logic. *See* FF ¶¶ 4-7.

23. I conclude that the analyses performed by Eco Logic will not aid the jury in reaching accurate conclusions under Rule 702. Furthermore, Eco Logic has altered an accepted methodology to such a point as to render its methodology unreliable under Rule 702 since Eco Logic failed to perform various steps which are significant and "absolutely essential" in the type of analyses employed. Eco Logic's unreliable methodology is unhelpful and thus excludable.

II. EXCLUSION BASED UPON RULE 703

24. Rule 703 of the Federal Rules of Evidence ("Rule 703") provides that:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

Fed. R. Evid. 703.

25. The proper inquiry is not what the court considers reliable, but what experts in the relevant discipline consider to be reliable. *Japanese Electronic,* 723 F.2d at 276 (citations omitted).

26. This Court has a "proper and reviewable foundation for making its admissibility findings," *Paoli,* 916 F.2d at 853, and has conducted the requisite factual inquiry under *Japanese Electronic* to determine what type of facts or data experts in the field of exposure assessment find reliable. 723 F.2d at 276.

27. "If a study's method of data collection is faulty, it may well be that no expert would rely upon the data generated as a basis for drawing any inference about the studied subject." *DeLuca,* 911 F.2d at 955 n.14.

28. I find that Dr. Peterson is well qualified to testify as to what data experts in the field of analytical chemistry rely upon to reach their conclusions. *See* FF ¶¶ 4-7.

29. Dr. Peterson stated that the matrix spike recovery rate should equal the surrogate recovery rate. The recovery rates of the spikes analyzed by Eco Logic were not the same. Dr. Peterson testified that this inconsistency indicates a problem in Eco Logic's quantitation. FF ¶ 30.

30. Quality assurance tells the analyst and other persons reviewing the data that it is reliable. FF ¶ 23. Dr. Peterson testified that there was no quality assurance data provided for the results obtained by mass spectrometry. There were no matrix or surrogate spike samples analyzed by mass spectrometry. Dr. Peterson stated that "[i]n absence of [this] recovery data, I don't think you can be confident in the results here." FF ¶ 32.

31. The purpose of calibrating instruments is to ensure that quantitation is done accurately. FF ¶ 33. The results of the analyses performed on Plaintiffs' samples by Eco Logic did not fall within the calibration range which was set up for the testing by the electron capture analysis. "[A]ll of the calibration standards were higher than any of the analyte concentrations which were measured." The calibration range was at times higher by a factor of two and at other times higher by a factor of 100. FF ¶ 34. Dr. Peterson also stated that the concentrations measured in Plaintiffs' samples fell below the calibration range in the mass spectrometer. FF ¶ 35. Dr. Peterson testified regarding the importance of having a calibration range which encompasses the levels measured in the actual samples, especially at the low levels measured in this case. "[I]t will affect your accuracy because you're not really sure how the instrument behaves at the very low levels, because you have no standards which have been run at that level." FF ¶ 36. Dr. Peterson stated that the effect of having sample results which fall outside the calibration range is that it makes Eco Logic's results "less accurate." *Id.*

32. In electron capture analysis, Dr. Peterson testified that it is essential to compare peak-by-peak the peaks on the DB5 column to the peaks on the DB17 column. He stated that a confirmation column is required in this type of analysis because if such a column is not used there is a great possibility of "misidentifying the individual congeners, not only as PCBs, but also misidentifying them

as some other compounds." Dr. Peterson testified that it is extremely possible that compounds other than PCBs are reported in the Eco Logic results and that he had little confidence that the identifications were correct due to the lack of confirmation. FF ¶ 37. Mr. Gierczak admitted that the purposes of the DB17 column is to prevent the potential misidentification of another compound. In addition, he stated that the DB17 column is critical to the overall analysis. Eco Logic's "Quality Control Manual" states that "the presence of an analyte is confirmed only when identified on both columns." Mr. Gierczak was unable to state whether any of the 15 PCB congeners listed in his affidavit had been identified on the DB17 column or on the mass spectrometer. FF ¶ 38.

33. There are certain congeners that appeared in both Eco Logic's mass spectrometry results and Eco Logic's electron capture analysis results. PCB 118 was run by both of these methods. The results on PCB 118 differed between these two methods by a factor of two, almost three. Dr. Peterson stated that this inconsistency points to a problem in the accuracy of the analyses. FF ¶ 39.

34. Dr. Peterson considered the data produced by Eco Logic on the six Plaintiffs to be unreliable. He also stated that he would not feel comfortable allowing data such as that produced by Eco Logic to be released from Pacific Toxicology Laboratories. FF ¶ 41.

35. I conclude based upon the entire record before me that the results of the analyses performed by Eco Logic on Plaintiffs' blood samples are not data of the type reasonably relied upon by experts in the field of analytical chemistry as required under Rule 703. Thus, all testimony concerning these results must be excluded.

36. I have concluded in a separate memorandum to exclude the testimony of Dr. Nisbet under Rules 702 and 703.

For the foregoing reasons, I conclude that the analyses performed by Eco Logic are unreliable under Rule 702. In addition, Eco Logic's results of the analyses performed on Plaintiffs' blood samples are not data which is reasonably relied upon by experts in the field of analytical chemistry under Rule 703. Thus, all testimony concerning these results must be excluded. I shall enter the following order:

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

George Burrell, et al v. *Septa, et al.*	No. 86-2235
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
Andre Williams v. *Septa, et al.*	No. 87-1258
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269

ORDER

AND NOW, this 21st day of October, 1992, upon consideration of Defendants' Motion *In Limine* to Exclude the Results of Analyses Performed by ELI Eco Logic Laboratories, Inc., all responses thereto, and a hearing on said motion, it is hereby ORDERED that said Motion is GRANTED.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.

APPENDIX IV-D

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

Mabel Brown v. *Septa, et al.*	No. 86-2229
George Burrell v. *Septa, et al.*	No. 86-2235
Wallace Cummins v. *Septa, et al.*	No. 86-2669
Sylvan Cohen, et al. v. *Septa, et al.*	No. 86-4037
K. Louise Jones, et al. v. *Septa, et al.*	No. 86-5277
James Lament v. *Septa, et al.*	No. 86-5886
Christopher S. Brown, et al. v. *Septa, et al.*	No. 86-7414
Cathlene Brown, et al. v. *Septa, et al.*	No. 86-7415
Craig Brown, et al. v. *Septa, et al.*	No. 86-7416
Margherita Barbetta v. *Septa, et al.*	No. 86-7417
Mary Retta Johnson v. *Septa, et al.*	No. 86-7418
Celeste Brown, et al. v. *Septa, et al.*	No. 86-7419
Clemmon Brown, et al. v. *Septa, et al.*	No. 86-7420
Cloyd H. Brown, et al. v. *Septa, et al.*	No. 86-7421
Curtis Brown, et al. v. *Septa, et al.*	No. 86-7422
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
Mary Alice Knight . *Septa, et al.*	No. 87-0712
William Butler, et al. v. *Septa, et al.*	No. 87-2874
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269
William Reid, et al. v. *Septa, et al.*	No. 87-5304

R.F. KELLY, J. October 21,1992

[As Amended February 1, 1993]

MEMORANDUM

MOTION IN LIMINE TO EXCLUDE REFERENCES TO DIOXIN, FURANS, TIN TETRAPHENYL, AND EPOXIDES

This is another of the many motions *in limine* filed by Defendants in the above captioned case. Defendants request that this Court exclude all testimony, evidence, or statements to the jury by Plaintiffs, their counsel or their witnesses concerning polychlorinated dibenzo-p-dioxins ("dioxin"), polychlorinated dibenzofurans ("furans"), tin tetraphenyl, and epoxide dicyclodiepoxy carboxylate ("EDDC").

All of the Plaintiffs or their decedents are or were residents of the neighborhood adjacent to the Paoli Railyard (the "Yard"). They allege injury and damage as a result of exposure to polychlorinated biphenyls ("PCBs") which were an ingredient of fire resistant fluid used in electrical transformers attached to the underside of the railroad cars which were serviced and maintained in the Yard.

These Plaintiffs allege that they were exposed to PCBs through dermal contact with soil contaminated by PCBs from the Yard, eating vegetables grown in gardens with soil contaminated by PCBs, and inhalation of windblown PCB-contaminated dust. None of these Plaintiffs claim exposure by virtue of having been employed in the Yard.

Plaintiffs intend to assert that they were also exposed to dioxin and furans because small amounts of those chemicals were detected in soil samples taken from inside the Yard. Plaintiffs also intend to assert that they were exposed to other chemical ingredients of PCB-containing dielectric fluid including tin tetraphenyl and EDDC [1] because small amounts of tin tetraphenyl and EDDC were included as intentional ingredients in PCB-

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[1] EDDC is one of a large class of chemicals known collectively as the "epoxides."

containing dielectric fluid. From the testimony taken on this and other motions *in limine*, deposition testimony, exhibits and record papers, this Court makes the following:

FINDINGS OF FACT

1. Tin tetraphenyl was an intended ingredient of the dielectric fluid used in transformers manufactured by General Electric Company from approximately 1944 to 1963. Its purpose was to serve as an hydrochloric acid scavenger. Tin tetraphenyl comprised only 0.125% of the total finished product composition. Rouse Dep. 194 and Exhibits 1 and 4 attached thereto.[2]

2. EDDC was an intended ingredient of the dielectric fluid used in transformers manufactured by General Electric Company from approximately 1963 to 1977. Its purpose was to serve as an hydrochloric acid scavenger. EDDC comprised only 0.125% of the total finished product composition. Rouse Dep. 194 and Exhibits 1 and 4 attached thereto.

3. There is no evidence in the record in this case that any soil samples taken inside the Yard were ever analyzed for the presence of tin tetraphenyl or EDDC. Indeed, the Plaintiffs have offered no evidence whatsoever that either tin tetraphenyl or EDDC was ever present at the Yard beyond the speculative inference that since they were an original ingredient of dielectric fluid then they might be present in the Yard.

4. There is no evidence in the record in that any of the soil samples taken from various locations in the neighborhood adjacent to the Yard, including the yards of some of these Plaintiffs, were ever analyzed for the presence of tin tetraphenyl or EDDC.[3]

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[2] "Rouse Dep." refers to the deposition testimony of Thomas Owen Rouse, Ph.D., taken on August 1, 1990 and July 22, 1991.

[3] Analyses of soil samples from the yards of several of these Plaintiffs were procured by Plaintiffs' attorneys, but they were

5. There is no evidence in the record in this case that any of the blood or adipose tissue samples taken from these Plaintiffs was ever analyzed for the presence of tin tetraphenyl or EDDC.[4]

6. There is no evidence in the record that either of the Plaintiffs' "exposure experts," Dr. Ian Nisbet and Dr. Melvyn Kopstein, performed an exposure analysis of any kind with respect to tin tetraphenyl or EDDC or attempted to quantify the extent to which any Plaintiff might have been exposed to tin tetraphenyl or EDDC. Indeed, there is not even a reference to these chemicals in either their extensive deposition testimony or their *in limine* testimony.

7. Plaintiffs' response to this motion completely fails to address Defendants' position with respect to tin tetraphenyl and is therefore deemed to admit and concede its correctness.

8. Although Plaintiffs' response to this motion asserts that the Defendants Monsanto, General Electric and Westinghouse "continued to use a methylated epoxide in transformer fluids, epoxide 201, well after they learned it could cause cancer," Plaintiffs' Response 57,[5] it does

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not analyzed for the presence of tin tetraphenyl or EDDC. *See* BCM Eastern, Inc. documents attached to Defendants' Reply Memorandum of Law in Support of Defendants' Motion *In Limine* to Exclude the Testimony of Plaintiffs' Expert, Melvyn Kopstein, Ph.D., dated and served on July 13, 1992.

[4] Plaintiffs' attorneys procured PCB analyses of blood and adipose tissue samples from many of these Plaintiffs, but did not include an analysis for the presence of tin tetraphenyl of EDDC. *See generally* Deposition and *in limine* testimony of Plaintiffs' experts, Drs. Sherman, Nisbet, DiGregorio, and Plaintiffs' Memorandum In Opposition To Defendants' Motions *In Limine* And In Support Of Plaintiffs' Motion To Strike, Dated July 8, 1992.

[5] "Plaintiffs' Response" refers to Plaintiffs' Memorandum In Opposition To Defendants' Motions *In Limine* And In Support Of Plaintiffs' Motion To Strike, dated July 8, 1992.

not address the Defendants' position that there is no evidence to establish that any of these Plaintiffs were ever exposed to EDDC or any other epoxide. It is therefore deemed that Plaintiffs have admitted and concede its correctness.

9. Unlike tin tetraphenyl and EDDC, there is evidence that dioxin and furans were measured in the Yard in very minute quantities. Approximately eighteen soil samples taken from inside the Yard were analyzed for dioxin and furans and their arithmetic average resulted in a dioxin toxicity equivalent of 0.603 parts per billion ("ppb"). This level is below the "CDC level of concern" of 1.0 ppb utilized by the Environmental Protection Agency in "The National Dioxin Study, EPA-440/4-87/003 (1987). *See* "Final Remedial Investigation and Risk Assessment," Paoli Railroad Yard, dated October 29, 1990.

10. There is no evidence in this case that any of the soil samples taken from various locations in the neighborhood adjacent to the Yard, including the yards of some of these Plaintiffs, were ever analyzed for the presence of dioxin or furans.[6]

11. There is no evidence in the record that any of the blood or adipose tissue samples taken from these Plaintiffs were ever analyzed for the presence of dioxin or furans. Plaintiffs' attorneys procured PCB analyses of blood and adipose tissue samples from many of these Plaintiffs, but did not include an analysis for the presence of dioxin or furans. *See generally* Testimony of Plaintiffs' experts, Drs. Sherman, Nisbet and Schecter. In addition, Plaintiffs' expert, Dr. Ian Nisbet, requested blood samples from six of these Plaintiffs and procured Eco Logic Laboratories, Inc. to perform congener specific

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[6] Analyses of soil samples from the yards of several of these Plaintiffs were procured by the Plaintiffs' attorneys, but they were not analyzed for the presence of dioxin or furans. *See* footnote, 2, *supra*.

analyses for PCBs but did not have the samples analyzed for dioxin, furans, tin tetraphenyl or EDDC. Likewise, Plaintiffs' expert, Dr. Janette Sherman, procured blood samples from ten of these Plaintiffs for the purpose of immunological testing by Antibody Assay Laboratories but never requested blood analyses for PCBs, dioxin, furans, tin tetraphenyl, or EDDC. Finally, this Court notes that these cases have been pending for at least 5 years or more and the Plaintiffs have had ample opportunity to have their blood or adipose tissue tested for the presence of dioxin, furans, tin tetraphenyl and EDDC (and at a time less remote from the period of alleged exposure), but not one has done so.

12. This Court heard *in limine* testimony on July 31, 1992, of Robert C. James, Ph.D., an Associate Professor at the Center for Environmental and Human Toxicology at the University of Florida and an author of approximately 50 publications in the field of toxicology, who was qualified as an expert in toxicology and pharmacology. James T. 74-81.[7] Dr. James testified that, in toxicology, the term "exposure" refers to "the eligilibity to have contact with the chemical," while the term "dose" refers to "the amount of chemical that's actually absorbed into the body." James T. 83. He explained that even when a person has been exposed to a chemical, it does not necessarily follow that the person has received a dose. He said: "There are a number of papers that have discussed and indicated that exposure is not a good measure of dose, and in fact, there is a recent paper by the Center for Disease Control that discussed this concept and problem in general, that we're finding particularly with environmental contamination that exposure extrapolation methods do not agree with actual measures of dose. And that unless dose extrapolation methods are then calibrated with some measure of dose, that they can

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[7] "James T." refers to the July 31, 1992, transcript of the *in limine* hearing in this action.

be misleading." James T. 83-84. Finally, Dr. James explained that the "[d]ose response relationship is the basic principle that toxicologists use to determine the safety or relative risk of a particular dose that a person has received. So it is a mathematical or graphical understanding of the doses over which the chemical produces no effect, and the doses that it produces whatever adverse effect that we're concerned with." James T. 85.

13. While Dr. Melvyn Kopstein did speculate how residential soils might have become contaminated with furans and dioxin, and how Plaintiffs might have been exposed to these chemicals, he admitted that he was unable to quantify any levels of residential contamination and does not believe that anyone could do a competent exposure analysis in this case. Kopstein T. 49-50, 58-61.[8] Furthermore, in his deposition, Dr. Kopstein conceded that there was insufficient data on residential contamination by dioxin and furans to perform a scientific computation of exposure: "there is *absolutely no data* that I've been able to find having to do with dioxin or furans off the site, and only sparse information about these chemicals on the site. So if you *don't really know what's present for sure,* and in what concentrations, then it's not possible to perform this type of computation." Kopstein Dep. 102 (emphasis added).[9]

14. There is no competent evidence in this case that these Plaintiffs were ever exposed to dioxin or furans because there is no evidence that these substances were present in the Yard in any significant amount or that they "migrated" off of the Yard and were present in the adjacent neighborhood or in the soil to which these Plaintiffs were exposed.

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[8] "Kopstein T." refers to the July 31, 1992, transcript of the *in limine* hearing in this action.

[9] "Kopstein Dep." refers to the deposition testimony of Melvyn Kopstein, Ph.D., taken on May 11, 1992.

15. There is no evidence in the record whatsoever that these Plaintiffs received any dose of dioxin or furans; that is, there is no evidence that these Plaintiffs had an up-take of dioxin or furans into their bodies.

16. The Court will judicially note that dioxin has received a great deal of adverse notoriety in the public press and has been described in the press as "the most toxic chemical known to man."

CONCLUSIONS OF LAW

1. The thrust of Defendants' motion *in limine* is that there is no evidence that the Plaintiffs in this case have received any internal dose whatsoever of the chemicals or have been externally exposed at all to dioxins, furans, tin tetraphenyl or epoxides. Plaintiffs argue in their response to this motion that: Defendants' contractor, GTI, failed to investigate for any toxic substance other than PCBs; dioxins and furans have toxic effects; and "certain heat producing operations" *i.e.*, burning, welding, etc., could have converted PCBs into other toxins such as dioxins and furans.

These responses totally ignore Defendants' argument that the soil samples from inside the Yard and from the surrounding properties were never tested for tin tetraphenyl or EDDC. Approximately eighteen soil samples taken from inside the Yard were analyzed for dioxin and furans and their arithmetic average resulted in a dioxin toxicity equivalent of 0.603 parts per billion in ("ppb"). This level is below the "CDC level of concern" of 1.0 ppb utilized by the Environmental Protection Agency in "The National Dioxin Study, EPA-440/4-87/003(1987). There is no evidence in this case that any of the soil samples taken from various locations in the neighborhood adjacent to the Yard, including the yards of some of these Plaintiffs, were ever analyzed for the presence of dioxin or furans. There is no evidence in this case that any of

the blood samples or adipose tissue taken from the Plaintiffs were ever analyzed for the presence of tin tetraphenyl, EDDC, dioxins or furans.

The issue then is not whether these categories of chemicals are harmful, the issue is whether there is any evidence in this case to indicate that they were present at all or present in quantities that could be deemed harmful. Plaintiffs response does not address that issue.

2. Rule 402 of the Federal Rules of Evidence ("Rule 402") provides that irrelevant evidence is inadmissible. The party offering evidence has the burden of establishing its admissibility. *Compagnie des Bauxites de Guinee v. Insurance Co. of North America,* 551 F. Supp. 12139 (D.C. Pa. 1982) (citing *Eastern Associated Coal v. Aetna Casualty & Surety Co.,* 632 F.2d 1068 (3d Cir. 1980)).

3. There is no evidence in the record that tin tetraphenyl or EDDC were ever present in the Yard or that these Plaintiffs were ever exposed to or received a dose of either of these substances.

4. There is no competent evidence in the record that these Plaintiffs were ever exposed to dioxin or furans because there is no evidence that these substances were present in the Yard in any significant amount or that they "migrated" off of the Yard and were present in the adjacent neighborhood or in the soil to which these Plaintiffs were exposed.

5. Further, there is no evidence in the record that these Plaintiffs received any dose of dioxin or furans; that is, there is no evidence that these Plaintiffs had an up-take of dioxin or furans into their bodies.

6. Therefore, evidence of the presence of dioxin or furans in very minute quantities in the Yard or the alleged adverse health effects associated with exposure to these substances would be irrelevant to the issues to be tried in Phase I of this trial.

7. Similarly, evidence of the presence of tin tetraphenyl or EDDC in the dielectric fluid as originally manufactured or any alleged adverse health effects assocated with exposure to these substances would be irrelevant to the issues to be tried in Phase I of this trial.

8. Rule 403 of the Federal Rules of Evidence ("403") provides that even relevant evidence may be excluded "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." When there is a risk that testimony and evidence may confuse or prejudice the jury, a party may properly file a motion *in limine* requesting the court to limit the scope of testimony. *Owens v. Concrete Pipe & Products Co.*, 125 F.R.D. 113 (E.D. Pa. 1989). Even where there is some evidence that trace amounts of these chemicals existed at the Yard, the trial court should exclude such findings where the probative value is outweighed by the danger of undue prejudice, confusion and delay. *In re Zenith Radio Corp. v. Matsushita Elec. Indus. Co., Ltd.*, 505 F. Supp. 1125 (1980), an antitrust action, factual findings from an investigation made pursuant to federal agencies' authority were inadmissible because they would invite irrelevant evidence and would result in a waste of time.

9. To permit the Plaintiffs, their witnesses or their counsel to present evidence concerning dioxin, furans, tin tetraphenyl or EDDC without any evidence that these Plaintiffs have been exposed to those substances would be prejudicial to the Defendants because they would be required to defend against a substance to which the Plaintiffs cannot prove they were exposed; confuse and complicate the issues for trial by necessitating the presentation of additional evidence to the jury to counter the allegations of exposure and health effects of substances to which the Plaintiffs cannot prove they were exposed; confuse and mislead the jury by focusing their attention on substances

to which the Plaintiffs cannot prove they were exposed; result in undue delay and wasting of time consumed in the presentation of irrelevant evidence at trial; and prejudice the Defendants by permitting inflammatory evidence concerning substances such as dioxin as to which there is much public sensitivity and fear.

10. The anticipated evidence concerning dioxin, furans, tin tetraphenyl and EDDC, even if relevant, is of such marginal probative value that it is clearly outweighed by the dangers enumerated in Rule 403 and analyzed above. Furthermore, the lack of evidence of exposure, the marginal probative value, and the prejudicial nature of the evidence make it unlikely that a limiting instruction would be effective.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

Mabel Brown v. *Septa, et al.*	No. 86-2229
George Burrell v. *Septa, et al.*	No. 86-2235
Wallace Cummins v. *Septa, et al.*	No. 86-2669
Sylvan Cohen, et al. v. *Septa, et al.*	No. 86-4037
K. Louise Jones, et al. v. *Septa, et al.*	No. 86-5277
James Lament v. *Septa, et al.*	No. 86-5886
Christopher S. Brown, et al. v. *Septa, et al.*	No. 86-7414
Cathlene Brown, et al. v. *Septa, et al.*	No. 86-7415
Craig Brown, et al. v. *Septa, et al.*	No. 86-7416
Margherita Barbetta v. *Septa, et al.*	No. 86-7417
Mary Retta Johnson v. *Septa, et al.*	No. 86-7418
Celeste Brown, et al. v. *Septa, et al.*	No. 86-7419
Clemmon Brown, et al. v. *Septa, et al.*	No. 86-7420
Cloyd H. Brown, et al. v. *Septa, et al.*	No. 86-7421
Curtis Brown, et al. v. *Septa, et al.*	No. 86-7422
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
Mary Alice Knight, v. *Septa, et al.*	No. 87-0712
William Butler, et al. v. *Septa, et al.*	No. 87-2874
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269
William Reid, et al. v. *Septa, et al.*	No. 87-5304

ORDER

AND NOW, this 21st day of Oct. 1992, the Defendants' Motion to Exclude All Testimony, Evidence or Statements to the Jury by Plaintiffs, their Counsel or their

Witnesses concerning Dioxin, Furans, Tin Tetraphenyl, and Epoxides, including EDDC or any alleged adverse health effects associated with or attributed to exposure to those substances, is hereby GRANTED.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.

APPENDIX IV-E

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master Docket No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

Mabel Brown v. *Septa, et al.*	No. 86-2229
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Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269
William Reid, et al. v. *Septa, et al.*	No. 87-5304

MEMORANDUM

R.F. KELLY, J. October 21, 1992

MOTION IN LIMINE TO EXCLUDE REFERENCES TO YUSHO AND YUCHENG

This is a toxic tort case brought by individuals who maintain that they have developed various illnesses as a result of their alleged exposure to polychlorinated biphenyls ("PCBs") from having either worked in or lived adjacent to the Paoli Railyard in Paoli, Pennsylvania. This Court held hearings on July 28, 29, 30, 31 and August 3 and 7, 1992 eliciting testimony and argument on the numerous motions *in limine* and dispositive motions filed in this action.

Defendants filed this motion *in limine* to exclude from trial all references to Yusho and Yucheng. Defendants argue that all references to the incidents that occurred concerning Yusho and Yucheng must excluded under Rules 402 and 403 of the Federal Rules of Evidence. Upon consideration of Defendants' Motion *In Limine* to Exclude References to Yusho and Yucheng, all responses thereto, the hearing and deposition testimony presented to this Court, and all exhibits admitted into evidence at the hearing, this Court makes the following Findings of Fact and Conclusions of Law:

FINDINGS OF FACT

1. In Japan in 1968, a large number of people ate rice oil used for food preparation which had been accidentally contaminated in the manufacturing process with a heat transfer fluid containing Japanese-manufactured PCBs. (Commonly referred to as "Yusho"). There were a number of reported adverse health effects attributed to the oral ingestion of this rice oil which included chloracne, pigmentation of the skin and nails, swelling and numbness of the limbs, jaundice, eye discharge, joint pain, head-

aches, fever and respiratory symptoms. *See generally* Kimbrough, "Human Health Effects of Polychlorinated Biphenyls (PCBs) and Polybrominated Biphenyls (PBBs)," *ment*, 1, 20 (J. Waid, ed. 1987).

2. Although early scientific reports linked these adverse health effects to PCBs, scientists later discovered that the rice oil also contained other, more toxic, chemicals, specifically polychlorinated dibenzofurans ("furans" or "PCDFs") and polychlorinated quarterphenyls ("PCQs"). *Id.*

3. In Taiwan in 1979, a similar accidental posioning occurred which involved approximately 2,000 persons who ate rice oil contaminated with Japanese-made PCBs which contained high levels of furans and PCQs. (Commonly referred to as "Yucheng"). These persons exhibited similar symptoms as those described by the Yusho victims. *Id.*

4. The scientific literature overwhelmingly concludes that the presence of furans in the rice oil proved to be the major etiologic agent in causing the adverse health effects observed in the persons exposed by oral ingestion in Yusho and Yucheng. "It has been concluded [that] PCDFs are the primary causal agent of Yusho as well as of the Taiwan incident [Yucheng]." Kashimoto and Miyata, "Differences Between Yusho and Other Kinds of Poisoning Involving Only PCBs," *PCBs and the Environment*, 1, 20 (J. Waid, ed. 1987).

5. Exposure to PCDFs furans and PCQs, as well as PCBs, make the Yusho and Yucheng incidents dubious for any scientific study of the effects of PCBs on humans. *See* W.R. Gaffey, "The Epidemiology of PCBs," *PCBs: Human and Environmental Hazards*, 279, 280 (1983).

6. According to the Agency for Toxic Substances and Disease Registry ("ATSDR"): "There appears to be general agreement that the PCDF contaminants, particularly the more potent isomers, contributed significantly to the

health effects observed in the Yusho and Yucheng patients." ATSDR, *Toxicological Profile for Selected PCBs*, § 4.1 at p. 44 (June, 1989).

7. As acknowledged throughout the medical and scientific literature by respected researchers, PCDFs/furans are the clear etiologic agent in Yusho and Yucheng. It is not valid to attribute any adverse health effects to PCB exposure based upon the Yusho and Yucheng data. *See id.*; Gaffey, "The Epidemiology of PCBs," *PCBs: Human and Environmental Hazards*, 279, 280.

8. At the *in limine* hearing, Defendants presented the testimony of Robert C. James, Ph.D. ("Dr. James"). July 31, 1992 Hearing Testimony of Dr. James ("James T."). Dr. James is an Associate Professor at the Center for Environmental and Human Toxicology at the University of Florida and an author of approximately 50 publications in the field of toxicology. Dr. James was offered by Defendants as an expert in the fields of Toxicology and Pharmacology. James T. 74-81.

9. Dr. James testified that Yusho refers to an incident in which cooking oil was heated under a vacuum to drive off odorants. The heat exchanger being used to heat the oil utilized a PCB-containing heat exchange fluid. The heat exchanger leaked fluids into the cooking oil which became contaminated. *Id.* at 85-86. Dr. James stated that a common pattern of clinical manifestations were observed in the Yusho victims. The primary manifestations were chloracne, a brown discoloration of the nails, swelling of the eyelids, cheesy discharge from the eyes, hyperemia of the eyes, and a general malaise. These manifestations appeared in the Yusho victims as early as 20 days and as late as 150 days. *Id.* at 86-87. Dr. James testified that the contamination in the Yucheng incidents occurred in much the same manner as in Yusho and the same clinical manifestations appeared. *Id.* at 86.

10. Dr. James stated that this pattern of manifestations had never been reported either in studies of persons

occupationally exposed to PCBs or in studies of non-occupationally exposed persons. *Id.* at 87. He stated that this is due to the fact that "Yusho and Yucheng were caused by polychlorinated dibenzofurans [furans]." *Id.*

11. Dr. James testified that the Yusho victims never had anywhere near the PCB levels that have been reported in capacitor workers. Moreover, he stated that after the Yusho victims' PCB levels returned to normal, their symptoms did not disappear while their furan levels remained elevated which easily explained all of the symptoms. *Id.* at 88. Dr. James testified that the Yusho and Yucheng incidents are not helpful in predicting human health effects from exposure to PCBs. *Id.* Yusho and Yucheng involved a different chemical. *Id.*

12. Dioxin and furans were measured in the Paoli Railyard (the "Yard") in very minute quantities. Approximately 18 soil samples taken from inside the Yard were analyzed for dioxin and furans. The arithmetic average from these samples resulted in a dioxin toxicity equivalent of 0.603 parts per billion ("ppb"). This level is below the Center for Disease Control ("CDC") level of concern which is 1.0 ppb. This CDC level is utilized by the Environmental Protection Agency in "The National Dioxin Study, EPA-440/4-87/003 (1987). *See* "Final Remedial Investigation and Risk Assessment," Paoli Railroad Yard, dated October 29, 1990.

13. There is no evidence in the record that any of the soil samples taken from the neighborhood adjacent to the Yard, including the yards of some of these Plaintiffs, were ever analyzed for the presence of furans.

14. There is no evidence in the record that any of the blood or adipose tissue samples taken from Plaintiffs were ever analyzed for the presence of furans. Plaintiffs' attorneys procured PCB analyses of many of the Plaintiffs' blood and adipose tissue samples but there were no analyses performed for the presence of furans. *See* Depo-

sition and *In Limine* Testimony of Drs. Sherman, Nisbet and Schecter.

15. These cases have been pending for at least five years. Plaintiffs have had ample opportunity to have their blood or adipose tissue samples tested for the presence of furans. Moreover, Plaintiffs have had ample opportunity to have soil samples from their yards analyzed for the presence of furans.

16. Dr. James testified that, in toxicology, the term "exposure" refers to "the eligibility to have contact with the chemical," while the term "dose" refers to "the amount of chemical that's actually absorbed into the body." James T. 83. He explained that even when a person has been exposed to a chemical, it does not necessarily follow that the person has received a dose. Dr. James stated that:

> There are a number of papers that have discussed and indicated that exposure is not a good measure of dose, and in fact, there is a recent paper by the Center for Disease Control that discussed this concept and problem in general, that we're finding particularly with environmental contamination that exposure extrapolation methods do not agree with actual measures of dose. And that unless dose extrapolation methods are then calibrated with some measure of dose, they can be misleading or inaccurate.

Id. at 84. Dr. James explained that "[d]ose response relationship is the basic principle that toxicologists use to determine the safety or relative risk of a particular dose that a person has received. So it is a mathematical or graphical understanding of the doses over which the chemical produces no [e]ffect, and the doses that it produces whatever adverse effect that we're concerned with." *Id.* at 85.

17. While Melvyn Kopstein, Ph.D. ("Dr. Kopstein") did speculate how residential soils might have become contaminated with dioxin and furans, and how Plaintiffs might have been exposed to these chemicals, he admitted that he was unable to quantify any levels of residential contamination and does not believe that anyone could do a competent exposure analysis in this case. July 31, 1992 Hearing Testimony of Dr. Kopstein at 49-50, 58-61 ("Kopstein T."). Furthermore, at his deposition, Dr. Kopstein conceded that there was insufficient data on residential contamination by dioxin and furans to perform a scientific computation of exposure: "there is absolutely no data that I've been able to find having to do with dioxin or furans off the site, and only sparse information about these chemicals on the site. So if you don't really know what's present for sure, and in what concentrations, then it's not possible to perform this type of computation." May 11, 1992 Deposition of Dr. Kopstein at 102 ("Kopstein Dep.") (emphasis added).

18. There is no competent evidence in this case that these Plaintiffs were ever exposed to furans. There is no evidence that these substances were present in the Yard in any significant amount or that they "migrated" off of the Yard and were present in the adjacent neighborhood or in the soil to which these Plaintiffs were exposed.

19. There is no evidence in the record whatsoever that these Plaintiffs received any dose of furans; that is, there is no evidence that these Plaintiffs had an up-take of furans into their bodies.

20. There is no evidence in the record that any of these Plaintiffs have ever been diagnosed as suffering from chloracne. The only testimony presented by Plaintiffs on this issue was that of Janette D. Sherman, M.D. ("Dr. Sherman") who diagnosed one Plaintiff as having contracted chloracne from exposure to PCBs. In a separate memorandum, I have concluded that Dr. Sherman was plainly not qualified to diagnose chloracne in any of

the Plaintiffs in this case. *See* Memorandum of this Court concerning Dr. Sherman, Findings of Fact 14-15, 37-39, 50. This Court granted Defendants' Motion *In Limine* to Exclude Opinion Testimony of Dr. Sherman under Rules 702, 703 and 403 of the Federal Rules of Evidence.

CONCLUSIONS OF LAW

1. In cases involving proffers of scientific evidence, the Third Circuit stated that "[i]t would appear that the most efficient procedure that the district court can use in making the reliability determination is an *in limine* hearing." *United States v. Downing*, 753 F.2d 1224, 1241 (3d Cir. 1985). The court went on to state that "[i]n the course of the *in limine* proceeding, the trial court may consider, *inter alia*, offers of proof, affidavits, stipulations, or learned treatises . . . in addition to testimonial or other documentary evidence (and, of course, legal argument)." *Id.*

2. The hearings held by this Court relating to Defendants' Motion *In Limine* to Exclude References to Yusho and Yucheng have produced a sufficient record to evaluate this evidence under Federal Rules of Evidence 402 and 403.

3. Rule 402 of the Federal Rules of Evidence ("Rule 402") provides that irrelevant evidence is inadmissible. Fed. R. Evid. 402. The party offering the evidence has the burden of establishing its admissibility. *Compagnie des Bauxites de Guinee v. Insurance Co. of North America*, 551 F. Supp. 1239 (W.D. Pa. 1982) (citing *Eastern Associated Coal v. Aetna Casualty & Surety Co.*, 632 F.2d 1068 (3d Cir. 1980)).

4. Defendants' main argument in support of its motion to exclude is that there is no evidence that Plaintiffs have received any internal dose whatsoever of furans or have been externally exposed at all to furans. Plaintiffs' response to this motion discusses the failure of Defendants' contractors to investigate for any toxic substance other

than PCBs. Plaintiffs argue the toxic effects of dioxin and furans, and they argue that "certain heat producing operations" *i.e.*, burning, welding, etc., could have converted PCBs into other toxins such as furans.

5. Plaintiffs simply ignore Defendants' arguments. Approximately eighteen soil samples taken from inside the Yard were analyzed for dioxin and furans and their arithmetic average resulted in a dioxin toxicity equivalent of 0.603 parts per billion in ("ppb"). This level is below the "CDC level of concern" of 1.0 ppb utilized by the Environmental Protection Agency. There is no evidence in this case that any of the soil samples taken from various locations in the neighborhood adjacent to the Yard, including the yards of some of these Plaintiffs, were ever analyzed for the presence of furans. There is no evidence in this case that any of the blood samples or adipose tissue samples taken from the Plaintiffs were ever analyzed for the presence furans. Moreover, there is no evidence in the record whatsoever that these Plaintiffs received any dose of furans; that is, there is no evidence that these Plaintiffs had an up-take of furans into their bodies. Findings of Fact ("FF") ¶¶ 12-14, 18-19.

6. Dr. James testified that the Yusho and Yucheng incidents are not helpful in predicting human health effects from exposure to PCBs. Yusho and Yucheng involved a different chemical. FF ¶ 11.

7. I conclude that the facts and circumstances of Yusho and Yucheng are substantially and significantly different from the circumstances involved in this case and these Plaintiffs. These differences include the following:

> (1) The Yusho and Yucheng victims had very high body levels of furans, whereas these Plaintiffs have no measured levels of furans in their bodies;
>
> (2) The principle route of exposure in Yusho and Yucheng was through eating cooking oil which was contaminated with furans, whereas these Plaintiffs

alleged a principle route of exposure through contract with contaminated soil;

(3) The Yusho and Yucheng victims were exposed to Japanese-manufactured PCB-containing heat transfer fluid that was made by a different manufacturing process;

(4) The length of time from exposure to manifestation of clinical symptoms in Yusho and Yucheng was from 20 to 150 days, whereas these Plaintiffs do not manifest these pattern of symptoms in a temporal relation to exposure; and

(5) The leading sign or illness exhibited by the victims of Yusho and Yucheng was chloracne, whereas there is no evidence in the record that any of these Plaintiffs have been diagnosed as having chloracne.

FF ¶¶ 1-4, 9-11, 14, 16-18, 20.

8. Therefore, I conclude that evidence concerning health effects experienced by Yusho and Yucheng victims is irrelevant to this case under Rule 402 and must be excluded. I find that this evidence is irrelevant to Plaintiffs' claims of adverse health effects from exposure to PCBs through soil contamination.

9. Rule 403 of the Federal Rules of Evidence ("403") provides that even relevant evidence may be excluded "if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403.

10. I find that to permit Plaintiffs to present evidence concerning the Yusho and Yucheng incidents or the health effects experienced by the victims of these incidents would be unfairly prejudicial to Defendants since Defendants would be required to defend against claims

of health effects resulting from exposure to furans and Plaintiffs have failed to provide any evidence that Plaintiffs were exposed to furans. Moreover, admission of this evidence will also confuse and mislead the jury by focusing their attention on circumstances and health effects caused by furans to which Plaintiffs cannot prove they were exposed. Furthermore, Defendants would be greatly prejudiced by this evidence since it concerns a widespread poisoning caused by a substance to which Plaintiffs cannot establish they were exposed.

11. I conclude that evidence concerning the Yusho and Yucheng incidents, even if relevant, is of such marginal probative value that it is clearly outweighed by the danger of unfair prejudice to Defendants and the danger of confusing or misleading the jury. I find that a limiting instruction would be ineffective in alleviating these dangers. Therefore, all evidence concerning the Yusho and Yucheng incidents must be excluded under Rule 403.

I shall enter the following order:

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Master Docket No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

Mabel Brown v. *Septa, et al.*	No. 86-2229
George Burrell v. *Septa, et al.*	No. 86-2235
Wallace Cummins v. *Septa, et al.*	No. 86-2669
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James Lament v. *Septa, et al.*	No. 86-5886
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Curtis Brown, et al. v. *Septa, et al.*	No. 86-7422
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
Mary Alice Knight v. *Septa, et al.*	No. 87-0712
William Butler, et al. v. *Septa, et al.*	No. 87-2874
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269
William Reid, et al. v. *Septa, et al.*	No. 87-5304

ORDER

AND NOW, this 21st day of October, 1992, upon consideration of Defendants' Motion *In Limine* to Exclude References to Yusho and Yucheng, all responses thereto, and a hearing on said motion, it is hereby ORDERED that said Motion is GRANTED.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.

APPENDIX IV-F

IN THE UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS MEMORANDUM RELATES TO:

Mabel Brown v. *Septa, et al.*	No. 86-2229
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Cathlene Brown, et al. v. *Septa, et al.*	No. 86-7415
Craig Brown, et al. v. *Septa, et al.*	No. 86-7416
Margherita Barbetta v. *Septa, et al.*	No. 86-7417
Mary Retta Johnson v. *Septa, et al.*	No. 86-7418
Celeste Brown, et al. v. *Septa, et al.*	No. 86-7419
Clemmon Brown, et al. v. *Septa, et al.*	No. 86-7420
Cloyd Brown, et al. v. *Septa, et al.*	No. 86-7421
Curtis Brown, et al. v. *Septa, et al.*	No. 86-7422
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
Mary Alice Knight v. *Septa, et al.*	No. 87-0712
William Butler, et al. v. *Septa, et al.*	No. 87-2874
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269

MEMORANDUM

R.F. KELLY, J. October 21, 1992

[As Amended February 1, 1993]

DEFENDANTS' MOTION TO PRECLUDE TESTIMONY OF DRS. CALESNICK, BARSOTTI, ZAHALSKY, NICHOLSON AND JENKINS

This is another of the many motions filed by Defendants in the above captioned case. Defendants request that this Court preclude Drs. Calesnick, Barsotti, Zahalsky, Nicholson and Jenkins from offering testimony on behalf of Plaintiffs. All of the Plaintiffs in this case or their decedents are or were residents of the neighborhood adjacent to the Paoli Railyard in Paoli, Pennsylvania. Plaintiffs maintain that they have developed various illnesses as a result of their alleged exposure to polychlorinated biphenyls ("PCBs") which were an ingredient of the fire resistant dielectric fluid used in the electrical transformers attached to the underside of the railroad cars which were serviced and maintained in the Yard.

Upon consideration of Defendants' Motion to Preclude the Testimony of Drs. Calesnick, Barsotti, Zahalsky, Nicholson and Jenkins and all responses thereto, this Court makes the following Findings of Fact and Conclusions of Law:

FINDINGS OF FACT

1. In their joint pretrial memorandum which was filed July 17, 1992, the Kohn/Klehr Plaintiffs and the Hanes Plaintiffs ("Plaintiffs") named three expert witnesses who were not identified in Plaintiffs' March 1992 Rule 26(b)(4) statements. These expert witnesses were Banjamin Calesnick, M.D. ("Dr. Calesnick"), Deborah Barsotti, Ph.D. ("Dr. Barsotti") and Arthur Zahalsky, Ph.D. ("Dr. Zahalsky").

2. Plaintiffs also named as fact witnesses in their joint pretrial memorandum two scientists who Defendants

argue have no known connection with the facts of this case and appear in reality to be expert witnesses. These proposed fact witnesses are William Nicholson, Ph.D. ("Dr. Nicholson") and Cate Jenkins, Ph.D. ("Dr. Jenkins").

3. On June 4, 1991, this Court entered a scheduling Order which required all Plaintiffs in this case to designate, on or before March 17, 1992, "all trial expert witnesses and provide defendants with the substance of their trial testimony and the basis of their opinions at the time of designation in accordance with Rule 26(b)(4)." This Order required the parties to identify and provide Rule 26(b)(4) statements for all trial experts including those who had previously submitted opinions for the 1988 summary judgment motion.

4. Plaintiffs failed to identify Drs. Calesnick, Barsotti and Zahalsky in accordance with this Court's Order of June 4, 1991. The first time that Defendants had notice of Plaintiffs' intention to call these experts at trial was on July 17, 1992 in Plaintiffs' joint pretrial memorandum. This disclosure was only two weeks from the scheduled trial date in this case of August 3, 1992.

5. Plaintiffs argue that these experts and their anticipated testimony have been well known to Defendants since 1988. However, this argument is not consistent with the fact that even though the Kohn/Klehr Plaintiffs had relied on the opinions of Ian C.T. Nisbet, Ph.D. in 1988, they produced another report from Dr. Nisbet and advised Defendants that they once again planned to proffer his testimony in accordance with this Court's June 4, 1991 Order. In addition, the Hanes Plaintiffs "re-designated" G. John DiGregorio, M.D., Ph.D. as a trial witness and stated that Dr. DiGregorio's opinions were as expressed in his 1988 deposition. Defendants likewise provided Rule 26(b)(4)

Statements for several experts who had rendered opinions in support of its 1988 summary judgment motion.

6. Defendants did not attempt to depose or redepose Drs. Calesnick, Barsotti and Zahalsky during the discovery period since these experts were not identified as trial experts in this case in accordance with this Court's Order. Defendants therefore did not move *in limine* to exclude the testmony of Drs. Calesnick, Barsotti and Zahalsky.

7. Defendants deposed all the purported expert witnesses on exposure and medical causation that were properly identified by Plaintiffs in this case and filed motions *in limine* to exclude the testimony of these experts under Federal Rules of Evidence 702, 703 and 403.

8. Defendants did depose Drs. Barsotti and Zahalsky back in 1988. However, under this Court's June 4, 1991 Order, Defendants were entitled to know by March 17, 1992 who Plaintiffs were calling as experts at trial and to depose or re-depose any of these experts during the expert discovery period.

9. Defendants have never deposed Dr. Calesnick. Dr. Calesnick offered an opinion in support of Plaintiffs' opposition to Defendants' 1988 motion for summary judgment. At that time, Dr. Calesnick submitted an affidavit where he stated that "the Plaintiffs have been exposed to PCBs," and that there was a "potential for them to sustain injuries from PCB exposure." Even Plaintiffs themselves disclaimed that Dr. Calesnick was being designated as a trial expert at that time. *See* Memorandum in support of Plaintiffs' Answer to Defendants' Joint Motion to Strike at 4, Filed September 23, 1988.

10. Dr. Nicholson was identified by Plaintiffs in their joint pretrial memorandum of July 17, 1992 as a "fact witness." Dr. Nicholson is a physicist who works in the Division of Environmental and Occupational Medicine at Mt. Sinai Hospital in New York. In 1988, Dr. Nicholson produced a "meta-analysis" of epidemiological data that

Plaintiffs submitted in support of their opposition to Defendants' 1988 summary judgment motion.

11. Dr. Jenkins was also identified by Plaintiffs in their joint pretrial memorandum of July 17, 1992 as a "fact witness." Dr. Jenkins is an EPA scientist and a purported authority on dioxins. Plaintiffs argue that jurors should be permitted to hear Dr. Jenkins' testimony since her testimony demonstrates the uncertainty that inheres in epidemiologic studies and Defendant Monsanto's disregard of the harms related to PCB-based transformer fluids which contain dioxins.

CONCLUSIONS OF LAW

1. Rule 37(b)(2)(B) of the Federal Rules of Civil Procedure provides that, as a sanction for a party's failure to comply with a discovery order, the court may issue an order "prohibiting that party from introducing designated matters in evidence."

2. The Third Circuit has made clear that preclusion of expert testimony is an appropriate sanction where the party proffering an expert has failed to comply with pretrial orders governing designation of experts or disclosure of expert opinions. *See Hagans v. Henry Weber Aircraft Distributors, Inc.*, 852 F.2d 60, 63-65 (3d Cir. 1988); *Semper v. Santos*, 845 F.2d 1233, 1237-38 (3d Cir. 1988).

3. Where preclusion of expert testimony would be equivalent to a dismissal of the case, the court must evaluate the circumstances pursuant to the six factors set in *Poulis v. State Farm Fire & Casualty Co.*, 747 F.2d 863 (3d Cir. 1984). *See Hagans*, 852 F.2d at 64. The *Poulis* analysis is not applicable to this motion because the preclusion of these recently identified experts is not in itself "tantamount to dismissal." *See id.*

4. Defendants attacked the admissibility of Drs. Barsotti and Zahalsky in 1988. The Third Circuit acknowl-

edged that these attacks were "forceful", however, the court went on to state that the record needed to be developed and the requisite factfinding under Rules 702 and 703 of the Federal Rules of Evidence was necessary. *See In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829, 859 (3d Cir. 1990), *cert. denied sub nom. General Elec. Co. v. Knight*, 111 S. Ct. 1524 (1991). Thereafter Plaintiffs never identified Drs. Barsotti and Zahalsky as trial experts pursuant to this Court's June 4, 1991 Order. Thus, these experts were not re-deposed and the record required by the Third Circuit was not established. Moreover, Defendants have never deposed Dr. Calesnick regarding his opinions or the methodology that he employed in rendering his opinions.

5. I conclude that Defendants have been severely prejudiced by Plaintiffs' failure to designate these experts in accordance to this Court's June 4, 1991 Order. The claims of all Plaintiffs in this case critically depend upon expert testimony concerning Plaintiffs' exposure to PCBs and the causal connection between this exposure and Plaintiffs' alleged injuries. The Order of this Court recognized the necessity of expert depositions in this case and allowed the parties to depose or re-depose opposing trial experts without further leave of the Court.

6. Since Drs. Barsotti, Zahalsky and Calesnick were never designated as trial experts, Defendants had no reason to depose or re-depose these experts regarding their opinions on Plaintiff. Moreover, Defendants never had an opportunity to challenge these experts' qualifications, methodology or data. Defendants had no knowledge that Plaintiffs intended to call these experts at trial until approximately two weeks before the scheduled trial date of August 3, 1992.

7. Plaintiffs' argument that these experts and their anticipated testimony have been well known to Defendants since 1988 simply fails. If Plaintiffs honestly believed that they did not have to redesignate experts that had previ-

ously proffered testimony in this case prior to the June 4, 1991 Order of this Court, then Plaintiffs would not have redesignated Dr. Nisbet and Dr. DiGregorio. Moreover, if these experts are not precluded, Plaintiffs will be significantly rewarded for their failure to designate these experts since Defendants have not had the opportunity to move *in limine*.

8. Plaintiffs shall not be permitted to proffer new experts on the eve of trial when their properly designated experts face exclusion. I conclude that Drs. Barsotti, Zahalsky and Calesnick must be precluded from testifying as expert witnesses in this case since Plaintiffs have failed to comply with the orders of this Court governing designation of experts and disclosure of expert opinions.

9. No other sanction could remedy the severe prejudice to Defendants. Defendants have been deprived of the opportunity to take discovery or further discovery of these experts' opinions on Plaintiffs and to file motions *in limine* to exclude their testimony. Reopening discovery or permitting these experts to testify without further discovery is not appropriate at this stage of the litigation and does not comport with judicial economy.

10. With respect to Drs. Nicholson and Jenkins, I conclude that these witnesses are expert witnesses not fact witnesses. Dr. Nicholson's testimony was regarded by the Third Circuit in *Paoli* as expert testimony. *See Paoli*, 916 F.2d at 856-59. The Third Circuit in determining the admissibility of Dr. Nicholson's "meta-analysis" reviewed his methodology under Federal Rule of Evidence 702. *Id.* Plaintiffs may not circumvent the procedures established by the Federal Rules and the orders of this Court regarding disclosure and discovery of expert testimony by merely identifying Dr. Nicholson as a "fact witness." In addition, the character of Dr. Jenkins' proposed testimony is not factual. Testimony regarding the uncertainty that inheres in epidemiologic studies is certainly not fact testimony but expert testimony.

11. Thus, since Drs. Nicholson and Jenkins were not properly designated as expert witnesses in this case, they must also be precluded from testifying.

Therefore, I shall enter the following Order:

IN THE UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

Master File No. 86-2229

IN RE: PAOLI RAILROAD YARD PCB LITIGATION

THIS DOCUMENT RELATES TO:

Mabel Brown v. *Septa, et al.*	No. 86-2229
George Burrell v. *Septa, et al.*	No. 86-2235
Wallace Cummins v. *Septa, et al.*	No. 86-2669
K. Louise Jones, et al. v. *Septa, et al.*	No. 86-5277
Christopher Brown, et al. v. *Septa, et al.*	No. 86-7414
Cathlene Brown, et al. v. *Septa, et al.*	No. 86-7415
Craig Brown, et al. v. *Septa, et al.*	No. 86-7416
Margherita Barbetta v. *Septa, et al.*	No. 86-7417
Mary Retta Johnson v. *Septa, et al.*	No. 86-7418
Celeste Brown, et al. v. *Septa, et al.*	No. 86-7419
Clemmon Brown, et al v. *Septa, et al.*	No. 86-7420
Cloyd Brown, et al. v. *Septa, et al.*	No. 86-7421
Curtis Brown, et al. v. *Septa, et al.*	No. 86-7422
John Ingram, et al. v. *Septa, et al.*	No. 86-7561
Mary Alice Knight v. *Septa, et al.*	No. 87-0712
William Butler, et al. v. *Septa, et al.*	No. 87-2874
Matthew Cunningham, et al. v. *Septa, et al.*	No. 87-5269

ORDER

AND NOW, this 21st day of October, 1992, upon consideration of Defendants' Motion to Preclude the Testimony of Drs. Calesnick, Barsotti, Zahalsky, Nicholson

and Jenkins and all responses thereto, it is hereby ORDERED that said Motion is GRANTED.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
J.